# EXHIBIT 3

VIDEOTAPED DEPOSITION BY VIDEOCONFERENCE
OF
GOURANG P. PATEL, B.S. CHEM, PHARM.D., MSc., FCCM, BCPS, BCCCP

February 11, 2022

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION
CAUSE NO. 3:18-CV-01234

TERRY LYNN KING, )
)
Plaintiff, )
)
-vs- )
)
TONY PARKER, et al., )
)
Defendants. )
_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _)

APPEARANCES

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# I N D E X

## THE DEPOSITION OF
## DR. GOURANG P. PATEL



## E X H I B I T S

E X H I B I T S

PLAINTIFF'S REFERENCED/MARKED

S T I P U L A T I O N

The deposition of DR. GOURANG P. PATEL, called as a witness at the instance of the Plaintiff, taken pursuant to all rules applicable to the Federal Rules of Civil Procedure, by agreement, on the 11th of February 2022, at each participant's respective location due to the COVID-19 pandemic, Tennessee, before Brenda L. Davis, LCR, RPR, RMR, pursuant to stipulation of counsel.

It being agreed that Brenda L. Davis, LCR, RPR, RMR may report the deposition in machine shorthand, afterwards reducing the same to typewriting.

All objections except as to the form of the question are reserved to on or before the hearing.

It being further agreed that all formalities as to notice, caption, certificate, transmission, etcetera, including the reading of the completed deposition by the witness and the signature of the witness, are expressly waived.

VIDEOGRAPHER: Good morning. We are going on the record at 9:03 a.m. on February 11, 2022. This is video unit number one of the video-recorded deposition of Dr. Gourang Patel, in the matter of Terry Lynn King versus Tony Parker, et al., filed in the United States District Court, Middle District of Tennessee, Nashville Division, Case Number 3:18-CV-01234. This deposition is being held remotely via Zoom.

Will counsel please identify themselves for the record.

MS. NELSON-MAJOR: Good morning. My name is Hayden Nelson-Major, I'm with the Federal Community Defender Office for the Eastern District of Pennsylvania. I represent the Plaintiff in this matter, Terry King. And also present with me in my office is my colleague, Anna Baldrige. On the Zoom from the Federal Community Defender Office is Lynne Leonard and Alex Kursman and Jules Welsh. Jules Welsh is a legal fellow with our office and does not represent Mr. King. Also present for Plaintiff's counsel is Jeremy Gunn with Bass, Berry & Sims.

MR. SUTHERLAND: Good morning, my name is Scott Sutherland, I'm a deputy attorney general with the Tennessee Attorney General's Office, on behalf of the Defendants Tony Parker and Tony Mays. With me from our office are colleagues Rob Mitchell, Dean Atiya, and that's it.

VIDEOGRAPHER: Will the court reporter please swear in the doctor.

DR. GOURANG P. PATEL

having first been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. NELSON-MAJOR:

Q. Good morning, Dr. Patel. Can you hear me okay?

A. I can, yes.

Q. As I just mentioned, my name's Hayden Nelson-Major, and I represent the Plaintiff, Terry King, in this matter. You have been retained by the attorneys who represent the Defendants to offer an opinion in this case; is that right?

A. That's correct, yes.

Q. And you understand that you're here today to answer some questions about opinions that you

offered in this matter; is that right?

A. Affirmative.

Q. I appreciate you taking the time to talk to us today. Do you understand what this case is generally about?

A. I do, yes.

Q. And what's your understanding of what this case is about?

A. My understanding is, it's about the utilization of lethal injection chemicals for the purpose of execution.

Q. And I understand that you've served as an expert witness before, but I just want to cover a couple of ground rules before we get started. You understand that you're under oath today.

A. I do, yes.

Q. And do you understand that means that you need to tell the truth to the best of your ability?

A. I do, yes.

Q. Have you taken any medications today that might affect your ability to recall facts or give accurate testimony today?

A. Negative.

Q. Have you consumed any drugs or alcohol in the past 24 hours?

A. Negative.
Q. And is there any reason that you believe you cannot testify truthfully or accurately today?
A. No, not that I'm aware.
Q. Are you represented by counsel today?
A. I believe that's correct, yes.
Q. And are you referring to Mr. Sutherland?
A. That's correct.
Q. And even though this deposition is being taken over Zoom, the court reporter is making a record based on what you say. So that means that you'll need to verbally respond to the questions, rather than gesturing. Do you understand that?
A. I do, yes.
Q. And so for the same reasons, I'll ask that you wait for me to finish my question before you start to answer. And I'll in turn try to do the same, I'll let you finish your answer before I answer -- before I ask the next question.
If you need to take a break at any time, just let me know. But if there's a question pending, I'll ask that you answer the question before we take that break. From time to time Mr. Sutherland might object to a question that I ask you. But unless that objection is on the basis of a

privilege, you still need to answer my question. Do you understand that?

A. I do, yes.

Q. Do you have any questions about those ground rules before we get started?

A. No.

Q. What did you do today to prepare -- excuse me, what did you do to prepare for your deposition today?

A. I reviewed a number of materials that would have been provided in the beginning and as the case has progressed, in addition to deposition transcripts, a number of reports that I've already cited in my report and some that I was provided -- that I obtained after my report was submitted.

Q. And what were the documents that you obtained after your deposition -- excuse me, after your report was submitted?

A. The documents that I reviewed after would have been inclusive of, I believe, at least a half dozen or so reports, if that. I believe they were from Dr. Van Norman, there was a Dr. Williams, Dr. Antognini. And, also, there was a supplemental, I think report, by Dr. Almgren which was submitted. And then there were some exhibits associated with

that.

Q. When did you review these documents that you just listed?

A. It would have been shortly after probably the supplemental or rebuttal report that I received. So it would have been whatever that date was.

Q. Do you know when you received these additional documents that aren't listed in your report?

A. It probably would have been sometime mid-January.

Q. And you mentioned that you reviewed a report from Dr. Antognini. Did you review one report from Dr. Antognini or multiple reports?

A. No, it was just one report.

Q. And other than the reports you just listed, did you review additional documents for the first time after you submitted your report in this case?

A. Other than those materials that I listed inclusive of -- there was quite a bit of materials reviewed prior. But, no, I don't recall outside of that.

Q. Did you review any depositions from the experts that you just listed?

A. Depositions? No, I haven't seen one.
Q. To prepare for the deposition today, did you meet with anyone from the Attorney General's Office?
A. No, I did not physically meet with anyone from the office.
Q. Did you have a Zoom or telephone meeting?
A. Yes, we had, I think, two or three phone conferences over the last 30, 45 days or so.
Q. And who from the Attorney General's Office was on those telephone calls?
A. It would be Mr. Atiya, Mr. Mitchell or Mr. Sutherland or a mix of their team.
Q. And when was the last meeting that you had?
A. We had one yesterday afternoon.
Q. And how long was that meeting?
A. Approximately 45 minutes, 50 minutes.
Q. And the other one to two meetings that you had, how long were those, approximately?
A. I'd say about the same amount of time.
Q. Did you review any documents during those meetings?
A. Documents? No.
Q. Besides the attorneys from the Attorney

General's Office, was anyone else present for those meetings?

A. Not that I'm aware of, no.

Q. You mentioned that you reviewed some expert reports to prepare for today. Did you also review other materials?

A. It would have been anything inclusive of, probably since the case started, which is on a ShareFile link.

Q. I'm sorry, repeat that again. I didn't catch that last part.

A. Sure. It would be any materials inclusive on the ShareFile link. It includes a number of documents from the State, it looks like quality control, quality assurance reports from the pharmacy that compounded the LICs, etcetera.

Q. And when you say a ShareFile link, is that like a Dropbox or a Box.com site?

A. Probably it's more secure. I believe it's through the State.

Q. And when you say that you reviewed quality assurance reports from the pharmacies that compounds drugs for TDOC, can you describe to me what those documents were?

A. Sure. They were inclusive of analysis for

testing, analysis and testing of the API, the final product, substituents, excipients, diluents used during the compounding of the LIC, and then any testing that was submitted upon the final product.

Q. Did those documents include a master log formula for any of the drugs that are compounded for TDOC?

A. I believe there is a couple of them that are compounded. Only two out of the three are actually compounded.

Q. And the documentation that you just cataloged, did it include the master log formulas for those two drugs that are compounded for TDOC?

A. That is my understanding, it was a formula sheet. I don't recall if it was called, "master log," but it was a formula sheet.

Q. Did that documentation also include logs that the pharmacy generated when compounding particular preparations for TDOC?

A. You'll have to define logs. I recall a formula sheet and a number of papers that were on that for analysis and testing before and after production, but that's all I remember.

Q. When a pharmacy compounds a preparation, do they document the steps they take to do that

compounding process?

A. Well, not necessarily. Because if you're familiar with sterile compounding, you have to be gowned and gloved up. So you can't actually document while you're doing the process, it's done after.

Q. After the compounding process is done, do compounding pharmacies generally document the steps that were performed?

A. That's correct. It can either be done on paper, electronically, or a sign-off. It just depends on the process the pharmacy has set up.

Q. Did you see paper or electronic forms that document the compounding process that the pharmacy did when preparing drugs for TDOC?

A. Not that I recall, no. Not to that detail.

Q. And the quality assurance documents that you referenced, were those provided to you prior to you drafting the report that you offered in this case?

A. That's correct.

Q. Did those documents also include logs from fingertip sampling tests performed by the pharmacy?

A. You're probably referring to media fill.

No, I did not see media fill testing.

Q. I was actually referring to the fingertip sampling first. Did you see records of that testing performed?

A. No.

Q. Have you reviewed any invoices documenting the purchases of drugs for TDOC?

A. If there were invoices inclusive of all the other documents I mentioned, if they were included in there then, yes, I would have reviewed them.

Q. But you don't recall whether or not you did, in fact, see those documents before?

A. Over the last three months, I'm sure they were -- if they were inclusive in there, then I reviewed them.

Q. And were the documents that you just listed provided to you at one time or were they provided to you over a series of times?

A. Which documents?

Q. You just listed a number of documents that were provided to you on the file share site. Were those documents provided to you all in one batch or were they provided to you in several batches?

A. I believe it's just all at one time.

Q. And that was prior to you authoring your report in this case.
A. That's correct.
Q. Have you reviewed any of the papers that have been filed in this case?
A. You'll have to define for me, what papers?
Q. Any court filings.
A. No, I don't -- I didn't review any court filings, or recall any.
Q. Did anyone consult with you to prepare for another deposition in this case; such as, the other experts retained by the Attorney General's Office?
A. We discussed the substance of my report and my opinions, and they were likely, I'm sure, used I'm other depositions.
Q. When you say, "we," you're referring to Mr. Sutherland, Mr. Mitchell or Mr. Atyia?
A. That's correct, because it was a Q&A and they asked me why my opinion was my opinion and I told them.
Q. But you didn't speak with Dr. Antognini or Dr. Li.
A. No, I haven't spoken with any of the experts. I don't know them.
Q. Did you discuss this deposition with

anyone other than the attorneys from the Attorney General's Office?

A. Negative.

Q. Did you do anything else to prepare for your deposition today other than what we just discussed?

A. No, ma'am.

Q. How much time in total do you estimate that you've spent preparing for today?

A. Over the last two, two and a half weeks, probably close to ten hours.

Q. Dr. Patel, do you have a copy of your report in front of you?

A. No, I do not.

Q. We're going to e-mail a copy to Mr. Sutherland, and I'm also going to share it up on the share screen, if you can sit tight for a moment.

All right. I'm going to share my screen with you. Are you able to see my screen share now?

A. I am, yes.

Q. Is this a copy of the report you submitted in this case?

A. That's correct.

Q. I'm going to mark this as Exhibit 1. I'm

going to turn to page three, and there's a heading: Materials Reviewed and Relied Upon. Is this a complete list of everything you reviewed when working on this report?

A. It's probably not a list of everything I've reviewed. It's inclusive of everything I reviewed and cited throughout the report.

Q. And as you just mentioned, there's some additional documents that you reviewed that aren't listed on this page, correct?

A. That's correct. I mean, the entire ShareFile is probably thousands of pages. I don't have everything listed there, no.

Q. So you're estimating that you reviewed several thousand pages of documents?

A. If you include 200, 300 pages per depo and all the other materials, it probably is, yeah.

Q. Were the documents that you provided -- that you were provided include the discovery that was produced in this case, if you're aware?

A. I don't know what it's labeled or called. But if they were included on the ShareFile, I reviewed them.

Q. Were you provided with records from executions that TDOC has previously conducted?

A. That's correct. Yes.
Q. Were you provided with training logs for training exercises that TDOC has conducted?
A. That's correct. I believe that was included in there as well.
Q. Were you provided with autopsy reports performed on individuals executed pursuant to TDOC's protocol?
A. Autopsy reports? No. I don't remember seeing any autopsy reports.
Q. So just so I understand, this section here, you've listed materials that you've reviewed and relied upon. But this is not a list of everything that you've, in fact, reviewed to date.
A. That's correct. Because some of the materials, as I just mentioned earlier, were after this report.
Q. Do you recall reviewing any records of pH testing performed on the drugs compounded for TDOC?
A. I don't recall exact pH testing logs, no.
Q. Have you reviewed any execution protocols other than the one at issue in this case?
A. No, ma'am, I have not.
Q. So no protocols from other states.
A. Other states? No.

Q. Have you talked to anyone at TDOC who is involved in carrying out executions?

A. No, ma'am.

Q. How about anyone at the pharmacy who supplies TDOC with lethal injection drugs?

A. No, I have not.

Q. Have you talked to anyone affiliated with TDOC about the potential use of drugs other than midazolam, vecuronium bromide, and potassium chloride for use at execution?

A. I have not, no.

Q. And have you spoken with anyone affiliated with TDOC about how to obtain drugs for use at executions?

A. No, I have not.

Q. I'm going to turn to page 11 of your report. And that should still be up on your screen, but let me know if it's not.

MR. SUTHERLAND: Ms. Nelson-Major, I have e-mailed the report to Dr. Patel. Dr. Patel, have you gotten your --

THE WITNESS: Let me see. Yeah, because it's a little bit hard to --

MS. NELSON-MAJOR: If it's easier for you to look at the pdf on your computer rather

than my share screen, that's fine by me.

THE WITNESS: Oh, okay. Thank you.

MR. SUTHERLAND: Did you receive the e-mail?

THE WITNESS: I did, Scott. Thank you. Yep.

MR. SUTHERLAND: Would you, please, review that in its entirety and make sure that -- just to acknowledge for the record that what you have is the report that you prepared?

THE WITNESS: That's correct. Yes, sir.

BY MS. NELSON-MAJOR:

Q. So if you turn to page 11, there's a numbered paragraph number one under the heading: Opinions. Let me know when you're there.

A. Okay.

Q. I'm looking at the first sentence under that heading Opinions, and you wrote, "My opinion is that TDOC's procurement and utilization of commercially manufactured and/or compounded LICs will not result in or cause the inmate to experience pain or suffering in the lethal injection execution process." Did I read that accurately?

A. That's correct.

Q. What about the fact that the drugs are either commercially manufactured or compounded leads you to the conclusion that the inmates will not experience pain or suffering?

A. It has to actually do more with the medications and their order and the doses that are utilized.

Q. And what does LIC mean in this sentence, for the record?

A. My understanding is that stands for in the protocol lethal injection chemical.

Q. Then the next sentence says, "TDOC's lethal injection manual describes the LIC being utilized for lethal injection are either FDA-approved commercially manufactured drugs or shall be compounded preparations prepared in compliance with pharmaceutical standards."

And in the footnote to that you cite page 34 of the protocol. I'm going to pull up the protocol, if you can hang tight. We'll e-mail it to you as well. Are you able to see the protocol on your screen now as well?

A. Just pulling it up. Give me one second. I see it, yes.

Q. And if you'd like to take a minute to look through it, that's fine. But does this appear to be the protocol that you were provided by Mr. Sutherland's office?

A. That appears to be the protocol, that's correct.

Q. I'm going to mark this as Exhibit 2, and I'm going to turn page 34, the page that you cited in that opinion, and I'm going to direct you to the paragraph at the bottom of the page.

MR. SUTHERLAND: I'm sending it to you now, Dr. Patel.

THE WITNESS: Thank you. That will be helpful. Thank you.

BY MS. NELSON-MAJOR:

Q. Are you able to read that paragraph? Or would you prefer to wait until you have the pdf in front of you?

A. I'll wait until I get the pdf, it'll be easier. Okay.

Q. If I could direct your attention to the full paragraph at the bottom of page 34 of the pdf, which states that, "Chemicals used in lethal injection executions will either be FDA-approved commercially manufactured drugs; or, shall be

compounded preparations prepared in compliance with pharmaceutical standards consistent with the United States Pharmacopeia guidelines and accreditation Departments, and in accordance with applicable licensing regulations."

What is the United States Pharmacopeia?

A. It's a private -- my understanding and experience is that it's a private organization that has developed guidelines for sterile and non-sterile compounding.

Q. And are they regarded as industry standards in compounding?

A. They are enforced in industry and, from my understanding, in hospitals or in pharmacies by the FDA. That's correct.

Q. And is it often referred to as USP for short?

A. That is correct.

Q. And what chapters of USP apply to the compounded drug preparations prepared for TDOC?

A. Well, there's a number of them, because it depends on which process you're talking about in the preparation. But, overall, the main one is probably USP 797.

Q. And what does USP 797 pertain to?

A. My understanding and experience is that it pertains to the preparation of sterile compounds.

Q. And what are sterile compounds?

A. Sterile compounds are, again, medications or drugs that are prepared by a hospital or a pharmacy pursuant to patient care.

Q. Are all injectable preparations considered sterile compounds under the USP?

A. Are all injectable preparations considered sterile compounds. Injectable -- that's correct, in the setting -- my understanding is that's specifically in the setting of diagnosis, care, treatment, and healing. That's true.

Q. And can you take a non-sterile ingredient and compound it into a sterile preparation?

A. Correct, that is performed and can be done.

Q. Returning to the paragraph on page 34 that we just reviewed, what does "accreditation Departments" mean in this paragraph?

A. Accreditation departments that -- at least that I'm familiar with, are -- because the USP, from my familiarity and experience, is -- they don't enforce actually anything. So the accreditation department, for example, for us in the hospital,

would be Joint Commission. So that -- at least that's my understanding.

Q. And what's the Joint Commission?

A. It's a regulatory -- it's not actually a regulatory body, it's a credentialing body for CMS. It's one of -- there's a couple of them that do this for institutions around the country, Joint Commission is one of them.

Q. So is it your understanding that "accreditation Departments" in this paragraph means that TDOC will comply with standards set forth by the Joint Commission?

A. No, that paragraph reads that the preparation standards are consistent with USP, or United States Pharmacopeia, and its guidelines and accreditation department. That has nothing to -- stated there what TDOC does or doesn't do.

Q. Is it your understanding that this "accreditation Departments" phrase requires the compounding pharmacy to follow standards set forth by the Joint Commission when preparing drugs for TDOC?

A. That's correct. Except compounding pharmacies aren't accredited by Joint Commission, they're usually followed by the state board.

Q. Without telling me the state, if you are aware, do you know where the compounding pharmacy is located?

A. You're asking if I know where the compounding pharmacy that actually prepares the LICs?

Q. Yes. But if you do, I'm not asking you to tell me the state. I'm just asking whether you know where the compounding pharmacy that compounds drugs for TDOC is located.

A. No, ma'am, I do not know.

Q. So you're not aware of which state board would oversee the compounding that occurs on TDOC's behalf.

A. No, ma'am, I don't know which state they're prepared in.

Q. So you don't know which accreditation department or set of licensing regulations would govern the compounded preparations that are provided to TDOC.

MR. SUTHERLAND: Objection to the form. You can answer.

THE WITNESS: Well, which accreditation department, it would fall within wherever the pharmacy -- the state it's located within.

So, no, I don't know.

BY MS. NELSON-MAJOR:

Q. And do licensing regulations vary from state to state?

A. That's correct.

Q. In rendering this opinion on page 11, did you assume that the pharmacy and TDOC followed applicable industry standards, including USP, when preparing drugs for use in executions?

A. No, I assume that the pharmacy preparing compounded preparations followed applicable USP standards as required.

Q. And would your opinion change if you were presented with information demonstrating that the compounding pharmacy and TDOC deviated from those standards?

A. In the setting and the scenario we're discussing, no, my opinion doesn't change.

Q. And why wouldn't it change?

A. Because there is actually a number of -- a number of reasons. The first and foremost has to do with actually how they're intended for use. So USP -- I believe it's on the first page even of the document. But, however, that last paragraph down there at the bottom states what USP does, what it's

intended for, and the goal of USP. My understanding is that it's pretty clear that it's in the setting of, again, diagnosis, care, treatment, and healing. This is not that setting.

Q. The protocol states that the drug shall be prepared consistent with the USP. But it's your opinion that the USP standards don't govern the preparations because it's not a clinical setting? Am I understanding that correctly?

A. It governs how the preparations are made by the pharmacy and pharmacist that prepare them, it does not necessarily govern how they're administered or their -- who's actually administering them because, correct, it is not a clinical setting in accordance with the other things that have been submitted.

For example, it does have testing of the compound identity and potency for the lethal injection chemical, it has testing for sterility. But, for example, endotoxin testing, from what I reviewed, was not present. But in my opinion, it doesn't change anything about how it's being used or the dose or the consequences to the person receiving it, if that helps clarify.

Q. Oh, and I'm sorry to cut you off,

Dr. Patel, I thought you were finished.

A. No, no, that's okay.

Q. So, in your opinion, only certain portions of the USP apply in this scenario.

A. It's not necessarily certain portions, it's consistent with -- based on the information we have, at least I have been provided and that we have currently, and the testing that was performed and how they're being utilized, prepared and administered, I do not believe it's going to be causing any additional -- or any pain or suffering to the person receiving the chemical.

Q. You mentioned endotoxins. I'd like to use that as an example. USP generally requires compounded preparations to be tested for the presence of endotoxins; is that right?

A. For non-sterile to sterile preparation, endotoxin is required, that is correct.

Q. And the compounding pharmacy is taking non-sterile ingredients to make a sterile preparation for TDOC; is that correct?

A. That is my understanding, that's correct, for two out of the three chemicals.

Q. But it's your opinion that, in doing so, the compounding pharmacy need not perform that

required test for endotoxins because you don't think it is relevant to this scenario; is that correct?

A. It's not necessarily that it need not be performed. It's more consistent with, if it wasn't performed, it won't have any consequences actually because of what endotoxin is and what it does.

Q. I'm going to return to your report for a moment. I'm looking at page 11 again. And I'm not sure if you can see my screen or if you'd rather pull it up yourself.

A. I'll just pull it up. Give me one second. Okay.

Q. So the next part of your opinion, you state, "Compounding pharmacies ensure that CSPs are correctly prepared, sterilized, packaged, labeled, sealed, stored, and dispensed."

Here are you making a statement about what compounding pharmacies should do?

A. That is the responsibility of the compounding pharmacy, that's correct.

Q. Do compounding pharmacies ever make errors in preparation?

A. I believe any institution or pharmacy that's preparing compounded sterile preparations, it is not devoid of an error, that's correct.

Q. And the same would be true for preparation, sterilization, labeling, sealing, storing, and dispensing?

A. That's correct, an error could occur in any points of that process, at any time.

Q. And have significant errors in compounding sterile preparations led to an increased call in regulation and monitoring of compounding pharmacies in recent years?

A. That's correct. The consequences that I'm familiar with are due to infection, which would manifest hours to days after. But that's correct, yes.

Q. And is that the only area in which you're aware of errors occurring at compounding pharmacies?

A. There have been errors with concentration. There have been errors with predominantly infection control, as I just mentioned, which have been probably the vast majority.

Q. I'm going to stop sharing my screen for a moment. As we were discussing, throughout your report you note that the protocol mandates that compounded preparations be compared -- excuse me, prepared in compliance with USP standards.

Does USP set standards for active

pharmaceutical ingredients?

A. USP has -- they're not standards, they're actually monographs for active pharmaceutical ingredients, that's correct.

Q. And what is an active pharmaceutical ingredient?

A. It's exactly as it states, it's the active ingredient that is going to go into the compounded sterile preparation. The USP is just one of probably four accepted ones that exist. Of course, in addition to the European, British, and Japanese Pharmacopeia.

Q. And compounding pharmacies in the United States, do they generally follow the USP when compounding preparations?

A. The com-- actual physical compounding of the preparation, that's correct, within the U.S. they're following the United States Pharmacopeia recommendations.

Q. You just mentioned monographs. What are the monographs?

A. Monographs are set up for the active pharmaceutical ingredients, or I'll refer them to as APIs, and those are set forth, again, by the United States Pharmacopeia, which are inclusive, for

example, of, again, the active ingredient, the -- it has to do with stability, the color, the dryness, or lack thereof, and then testing, which is done on a number of different -- testing for not just the active chemical but a number of different impurities within the API itself.

Q. So each monograph sets particular quality requirements for a specific drug; is that right?

A. That's correct, that is the standard across the USP, the British Pharmacopeia, the European Pharmacopeia, and the Japanese Pharmacopeia, from my understanding.

Q. And does the monograph also specify the methodology that is to be used when measuring each quality requirement?

A. That's correct, each one of those pharmacopeias which is intended for compounded sterile preparations for humans within that country dictates and outlines what their criteria are and how they will be tested.

Q. And how does a compounding pharmacist use that monograph?

A. A compounding pharmacist is probably most often utilizing the Certificate of Analysis that has been performed on the API, and they're reviewing the

Certificate of Analysis that's already been performed prior to beginning their compounding process.

Q. And what's a Certificate of Analysis?

A. The Certificate of Analysis is actually sent from the manufacturer of the API, which is inclusive of all those variables I discussed earlier.

Q. So it documents the test results performed?

A. That's correct. It documents a number of things, including identification of the compound, any issues with the color or how it should actually appear when it was produced and sent out, and, again, any testing for impurities that was done respective of which compound that they're actually sending it out with.

Q. And what does it mean for something to be USP grade?

A. USP grade means it has been verified against the USP monograph, from my understanding.

Q. And so in order for API to be considered USP grade, it has to meet all of the standards set forth in the monograph for that particular API?

A. That's correct.

Q. And you've mentioned some of these quality requirements. I just want to ask you about a couple of them. What does identification mean?

A. Identification is identifying the active pharmaceutical ingredient and, depending on the compound, it outlines a percentage, which, again, is pretty much universal across the four pharmacopeias.

Q. And what is assay?

A. Do you mean assay?

Q. I do mean that.

A. Oh, sorry.

Q. I'm new to this terminology. Please excuse me.

A. No, I wanted to make sure it wasn't a different term. The assay is basically the testing that's performed on the active pharmaceutical ingredient. And the assay is, again, after the type of testing required. From what I recall, the different amounts and testing that are done with the products here at question can be either high-performance liquid chromatography or liquid chromatography or infrared spectrometry, or IR.

Q. And those three methods you just mentioned are three different ways of testing the assay?

A. That's correct.

Q. Is assay the same thing as potency?
A. Identification -- the identifi-- I believe the entire first part of that states identification assay. But that's correct, it lists not necessarily -- it's semi-equivalent to potency. But it's how much percentage of the true active pharmaceutical ingredient is in that container when it's received, or shipped out.
Q. And those measures, taken together, tell you whether what's inside the vial is of the strength it's supposed to be; is that correct?
A. Well, for -- are you asking about the API still? Or are we talking about the final prepared CSP?
Q. I'm still asking about the API.
A. Oh. Then it just is the active pharmaceutical ingredient. And those are -- from what I understand, they could be in vials, larger vials, or they're in, generally, bulk containers.
Q. And another quality requirement that I think I heard you mention was drying. Can you explain that to me as well?
A. Sure. It has to do with the amount of humidity, as that can impact the active pharmaceutical ingredient before it's used for

preparation. It's pretty standard with any bulk chemical and generally for powders.

Q. And is endotoxins another quality requirement that the USP generally says should be tested on API?

A. That is in there as well. And endotoxin, again, is defined as the amount of dead bacteria that can generate a pyrogen response, which is -- in layman terms, is a fever.

Q. And what about impurities, is that another quality requirement?

A. That is, impurities are a quality requirement. And as I had mentioned, it's fairly standard across the four pharmacopeias, they just do it a little bit differently.

Q. And how is it done differently across the pharmacopeias?

A. It depends on which pharmacopeia you actually go with. So, for example, European Pharmacopeia, again, established in Europe for treatment of -- utilizing the APIs and CSP preparation for treatment of humans in Europe, has the impurities -- for example, of midazolam, if we look at the eight impurities on the USP monograph and put it side by side by the European monograph,

the European monograph actually tests for one additional impurity that the USP does not. So they actually cover the exact same impurities, they're almost verbatim. I think the USP had a total of eight and, if I recall correctly, European tests for nine.

Q. And the information about all these quality measures, you stated, is provided on a Certificate of Analysis for the API; is that accurate?

A. The monograph is not on the Certificate of Analysis. The Certificate of Analysis is the testing that's associated with the monograph. But that's correct, it's provided, from my understanding, with the shipment of an API.

Q. And so when a compounding pharmacy purchases API, the manufacturer of the API provides that Certificate of Analysis to the compounding pharmacy.

A. That is correct. That is the standard operating protocol, or SOP.

Q. So you've mentioned some of the other pharmacopeias out there, you mentioned the British Pharmacopeia, the European Pharmacopeia, and the Japanese Pharmacopeia. Are those the other three

main pharmacopeias that you're aware of?

A. Well, there are more. But those three in addition to the U.S. pharmacopeia is the one the USP most often associates with its standards. And that's why I said those are the four that are fairly equivalent across the board. That's correct.

Q. But there are differences in acceptable values for the same criteria amongst the different pharmacopeias. Is that also accurate?

A. From my understanding and review, they're almost all verbatim spot on. But if there's a percentage difference of 0.01 in an impurity of one versus a 0.15 of another, I would say that's negligible. But that would be a difference, that's correct.

Q. But there could be a circumstance in which a drug API is tested, passes the USP, but fails the European Pharmacopeia based on the differences in values; is that right?

A. My understanding is, is that for the impurities, it's just actually how they're performed. So, for example, the USP would test for the individual impurities. The European Pharmacopeia has additional testing that's already picking up the other eight impurities, so they don't

have direct percentages associated. But that's correct, it could pass on one and not on another.

Q. And I understand that you're saying that impurity quality requirement has very little differences, in your opinion, between USP and the European Pharmacopeia. I'm asking a more general question, which I think you answered in the affirmative, is that could one drug -- the same drug pass under the European Pharmacopeia but fail under the USP pharmacopeia. And I think your answer was yes. Am I right?

A. That's correct, the reverse is also true. So it can pass on a European, British, or Japanese Pharmacopeia and fail the USP.

Q. And I think you mentioned this as well. But there are differences in the methodologies required under the European Pharmacopeia, the USP, the BP for the same test. Is that also true?

A. As a general statement, yes. For the chemical in question, no, they're identical.

Q. And what's the chemical in question?

A. Well, the potassium chloride certificate I reviewed stated USP. So the only one in question is midazolam.

Q. And so you disagree with Dr. Almgren's

analysis of the differences between the USP monograph, the EP monograph, and the BP monograph for midazolam. Is that what you're saying?

A. I would respectfully disagree, that's correct. If you put them up side by side and actually go through the testing and the analysis, the European Pharmacopeia, as I had mentioned, if you do that, actually picks up an additional impurity that the USP does not.

Q. And, in your opinion, is it irrelevant that the USP, the EP, and the BP require different testing methodology for assessing that value?

MR. SUTHERLAND: Objection to the form. Did you say relevant or irrelevant?

MS. NELSON-MAJOR: Irrelevant.

MR. SUTHERLAND: Could you rephrase the question, Hayden. I'm sorry.

BY MS. NELSON-MAJOR:

Q. So my question, if there are differences in methodology between the three pharmacopeias, in your opinion, that's irrelevant to the actual conclusion that they're equivalent.

A. If there are true differences in the methodology, my understanding is, at least reviewing the only chemical in question that it would be

applicable to, it is irrelevant. Because if we put them side by side, USP uses liquid chromatography, European uses liquid chromatography, USP recommends infrared, or IR, identification, European already has on the first line IR. They're almost virtually the same, or equivalent.

Q. I'm so sorry, Dr. Patel, I thought you were finished.

A. That's okay.

Q. And when you're preparing compounded drugs in a clinical setting, do you use the methodologies set forth in the USP when you are doing these quality assessments on your drugs?

A. The USP is what's recommended, that's correct.

Q. And if you're compounding a USP-grade preparation, are you free to pick and choose the methodology for a particular quality requirement, or do you have to follow the methodologies set forth in USP?

A. If I'm compounding it, again, in the setting of diagnosis, care, treatment, and healing, I would be following the USP recommendations, that's correct.

Q. Why?

A. That is what's required within the setting of hospitals and/or stand-alone pharmacies in the setting of diagnosis, treatment, healing, and caring.

Q. In your experience, do manufacturers located in the United States who make API for compounding pharmacies in the United States subject their API to USP standards?

A. My understanding is, that's correct. Except if we look at the actual bigger picture, then everybody's familiar with that the majority of U.S. owned companies manufacturing are actually not stateside, they're abroad.

Q. And why wouldn't such a pharmacy in the example that I just gave you use EP or BP standards when selling API to a compounding pharmacy in the United States?

A. They are held to where the manufacturing plant is. If it's within Europe, then it'd be the European Pharmacopeia, and that's what would be coming with the API. If it's coming from the UK, it would have the BP Pharmacopeia. If it's coming from Japan, it would have the Japan Pharmacopeia. Because that's what's required, again, for the treatment of -- diagnosis, treatment, care, and

healing for humans within that country or state.

Q. And that phrase that you've used several times, can you -- "the treatment, care, and healing of humans" -- am I accurately paraphrasing that?

A. That's correct. That's my understanding of why the USP, pharmacopeia, was developed. It's in, again, the last paragraph on the first page.

Q. And are you suggesting that the USP standards don't govern the drugs compounded for TDOC because we're not talking about the treatment, care, and healing of humans?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: The standards apply to how the preparations are -- again, how the compounded sterile preparations are prepared and stored and dispensed. They do not apply to TDOC, nor anybody on the TDOC premises.

BY MS. NELSON-MAJOR:

Q. The question I'm asking is, whether those standards apply to the compounding pharmacy that is preparing the sterile preparations for TDOC.

A. If that compounding pharmacy is within the U.S., then yes, it would apply to them.

Q. I'm going to pull up one of the Certificate of Analysis that you've alluded to, if

you could hang tight with me. I'm going to share my screen again, but you also have this sent to you in the e-mail. Are you seeing that on your screen now?

A. Let's see.

Q. You'll probably have to zoom out to the right proportion. I'm not sure how it's showing up on your screen.

MR. SUTHERLAND: Dr. Patel, I'm forwarding you the pdf as we speak.

A. No problem. I got it. Okay.

Q. You've seen this Certificate of Analysis before, right?

A. I believe -- yes, I have.

Q. I'm going to mark it as Exhibit 3. Can you see that under "CERTIFICATE OF ANALYSIS" it says, "MIDAZOLAM, EP"?

A. I do, yes.

Q. And then I'm going to scroll down to the bottom of the page, where it states, "The above mentioned product conforms to the specifications of EP."

Does that indicate to you that this API was subjected to European Pharmacopeia standards?

A. That's correct, that testing was performed aligned with the European Pharmacopeia.

Q. So this Certificate of Analysis does not confirm that the API meets USP standards on the face of the document; is that correct?

A. That's correct, it is not on USP monograph.

Q. And the fact that it's not based on USP monograph means that this API cannot be considered USP grade. Is that also correct?

A. That is correct.

Q. Does the fact that the API was subjected to EP standards indicate that it was purchased from a European source?

A. That means -- I don't understand the -- quite -- purchased from a European source. My understanding is that the manufacturer is likely overseas.

Q. Do compounding pharmacies generally purchase API from the manufacturing source?

A. That's correct. Unless the API is available through their wholesaler.

Q. And what's a compounding pharmacy wholesaler?

A. A wholesaler, in layman terms, is the middleman.

Q. When you're searching for API, do you

generally contact your wholesaler first?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: Sure. It depends on the product, the medication, and availability.

BY MS. NELSON-MAJOR:

Q. And if your wholesaler doesn't have a particular API available, what do you do next?

A. You can try to find an actual manufacturer that prepares APIs.

Q. And how do you find manufacturers?

A. There would be a database that's usually associated with the wholesaler website. And so if you type in, for example, the API active ingredient, it could give you a list of any number of manufacturers that potentially prepare this worldwide.

Q. And when you search a database that you just mentioned for API, do you have to specify that you're looking for API versus commercially manufactured drugs?

A. I'm not quite sure I understand. If you're searching for API, that means the -- likely, maybe the compounding pharmacist or pharmacy has already tried to find a commercially manufactured

product.

Q. I'm going to pull up another Certificate of Analysis. Hold tight for a moment. And we'll e-mail this to you as well.

Can you see the document that I just pulled up on your screen?

A. Yeah, it's pretty hard to read. I'll just wait for the -- yeah, it'll be easier.

MR. SUTHERLAND: I'm still waiting for it, Ms. Nelson.

MS. NELSON-MAJOR: Did that come through to you yet, Mr. Sutherland?

MR. SUTHERLAND: It has not.

BY MS. NELSON-MAJOR:

Q. Dr. Patel, I'm not going to ask you about any of the small print at the bottom of the page. I'm really just looking at the top. So if you're able to see that and are comfortable proceeding that way, I'm fine. But if you'd rather wait, by all means, we can wait.

A. If you can make it large, that would help. Okay.

Q. Is that better?

A. Much better, yes.

Q. Have you seen this document before?

A. Yes.
Q. And it says, "CERTIFICATE OF ANALYSIS" at the top?
A. That's correct.
Q. And it looks like it says it has a manufacturing date of February 1, 2016?
A. That's correct.
Q. I'm going to mark this as Exhibit 4. And do you see under "CERTIFICATE OF ANALYSIS" it says, "MIDAZOLAM, BP"?
A. That's correct.
Q. Does that indicate to you that this API was subjected to British Pharmacopeia standards?
A. That is my understanding, yes.
Q. And so like the other Certificate of Analysis, this document doesn't demonstrate that this midazolam API is USP grade?
A. That's correct, it was not tested against USP monograph.
Q. Does the fact that this API was subjected to BP standards indicate to you that it was purchased or manufactured by a British source?
A. Again based on my training and background and experience, is that the manufacturer is likely located in the UK.

Q. And when you say likely, are you suggesting that there's another explanation for why this was subjected to BP standards?

A. No, that's just based on my background, training and experience, that's what I would assume.

Q. I'm going to take this down.

MR. SUTHERLAND: I just received this and I'm going to forward it to Dr. Patel.

Q. Dr. Patel, would you like to take a look at that Certificate of Analysis just to confirm your prior statement?

A. That's correct, I can take a look at it real quick, that's not a problem. That's correct.

MS. NELSON-MAJOR: And, Mr. Sutherland, I know that you said you would like to take a break at 11:00 o'clock your time, 12:00 o'clock our time. Are you fine with pushing through until then? Or would you like to take a break, Mr. Sutherland or Mr. Patel, at this point?

MR. SUTHERLAND: Fine pushing through. Dr. Patel, what's your preference? Are you okay?

THE WITNESS: I'm fine.

BY MS. NELSON-MAJOR:

Q. And as I mentioned earlier, if at any point you do need to take a break, just let me know, and we'll be happy to accommodate that.

In your report you note that, "The Pharmacist outlined the procedure for sending the sample of the CSPs for testing in regard to potency/strength and sterility as recommended by USP standards."

Are sterility, potency and strength all of the quality requirements that USP imposes on testing?

MR. SUTHERLAND: Ms. Nelson-Major, if I could interject. Could you refer Dr. Patel to where you're --

MS. NELSON-MAJOR: Absolutely.

MR. SUTHERLAND: -- talking about?

BY MS. NELSON-MAJOR:

Q. Let's turn to page 12, the first full paragraph. And I'll direct you to the sentence again. It's the first sentence of the first full paragraph on page 12. You wrote, "The Pharmacist outlined the procedure for sending the sample of the CSPs for testing in regard to potency/strength and sterility as recommended by USP standards."

And my question was, are potency and sterility the only quality requirements recommended by USP?

A. The additional one is endotoxin.

Q. What about pH? Does the USP require compounded preparations to be tested for pH?

A. That's correct. But it's actually outlined for sending the sample. They're only -- you only need to send it for, my understanding, potency or strength, which is really identification, sterility, and the presence of endotoxin, which, again, as I mentioned, is a trigger for fever. The pH is actually performed at the end of preparation.

Q. And what do you mean by, "the end of preparation"?

A. After the compounded sterile prep, or CSP, is completed, the pH testing is usually the last thing done by the pharmacist or the technician.

Q. If a drug that you compounded failed one of the required USP standards, would you release it for use on a patient?

A. If the drug failed testing, no, it would not be sent for use for a patient.

Q. Why not?

A. The reason is, is that -- it actually

depends on which standard failed as well. But for the most part, the ones that end up flagging are either potency or sterility. And the reason is, of course, potency could be less concentrated or more concentrated than what was prescribed. And sterility and/or endotoxin have to do with the presence of bacteria, which means there could be a risk of infection hours or days after administration.

Q. And if when you tested a CSP for pH and it was outside the acceptable range, would you release that to a patient?

A. If the pH was outside the range, it would not be released, because the pH has to do with the stability and solubility of the CSP.

Q. What about if you didn't get a pH test result back, would you release that drug for use on a patient?

A. If we didn't get a pH test back. Well, the CSP isn't sent for pH, the CSP is -- the pH, as I mentioned, is done right after preparation, then the CSP, from at least my understanding, is sent out.

Q. My question is, if you in a clinical setting tested a final preparation for pH, but for

some reason the results were lost, would you still nonetheless release that drug for use on a patient?

A. If the pH result was lost, no, we would not release it for patient care.

Q. Why not?

A. Again, because it has to do with the stability or solubility of the actual preparation. The reason that this is critical is that many of these things are stored long term and so the stability and/or solubility are important, which is why the pH testing is done.

Q. Does pH have any impact on how the drug feels to a patient when it's administered?

A. Not to my understanding, no. The actual proper use of pH is, again, stability and solubility. Drug administration, the only time I'm aware of pH being a factor is actually if it extravasates, which, if you're familiar with the term, meaning the drug getting outside the vein.

As long as the drug is in the vein, an antecubital large vein, which I believe a antecubital fossa is utilized, it is not an issue. And the reason, again, it's my opinion, is if we look at a number of -- just take anesthetic drugs, the pH's go as far as two and as high as nine.

So if what you just stated was actually scientifically and methodologically true, we wouldn't have any drugs to use for patient care.

Q. And so the only reason pH is tested on a final product is for long-term stability concerns?

A. That is the two main reasons, that's correct, of utilizing and testing for pH of a CSP. Injection upon pain site is not a reason that you're testing for pH, as I already described.

Q. And so you could inject a prepared drug into a patient's peripheral IV regardless of the pH of that final product.

A. The injection pH, again, it's more of a concern -- or really any concern if the drug extravasates; meaning, it gets outside the vein. So, for example, Dilaudid, hydromorphone, has a pH identical to midazolam, between about two and three. Phenobarbital, as an example, has a pH between nine and ten. So if that scientific methodology was true, we wouldn't have any drugs to inject in patients. So, no, it's not an issue.

Q. And the risk of -- and excuse me if I get this word wrong -- extravasation, which is essentially leakage outside of the vein, does that concern factor into the way that pH is adjusted in

the lab setting?

A. It would only be applicable to drugs with a pH of, my understanding, less than five or greater than nine, which is pretty much virtually everything we use in patient care.

Q. Returning to the LIC that's compounded for TDOC. Was all of the LIC that was prepared by the compounding pharmacy in fact subjected to the required tests under USP?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: Sure. My understanding is, again, the -- from what I have -- we have available, the identification and potency was tested, the sterility was tested; however, the endotoxin test, as I had mentioned, was absent.

BY MS. NELSON-MAJOR:

Q. And you've seen documentation that sterility test was performed on all the compounded preparations that you've seen documentation of?

A. I've seen the testing performed on midazolam and/or potassium chloride, which have, of course, associated potency or strength and/or sterility tests. And we have to also kind of think

about how the tests are performed, which wasn't discussed in any of the reports. Generally, it's a sequence.

So, for example, the potency and/or sterility are performed. The endotoxin, from my understanding, is an incubation. So that's why the dates are all different. And for some reason the dates are sometimes even seven to ten days apart, as they should be, because the incubation time is generally about -- within about a two-week time period.

Q. And you've seen reports from the lab documenting the results of endotoxin testing on the drugs compounded for TDOC?

A. There are endo-- there is endotoxin testing with, I believe, at least one midazolam sample. And I can't recall if it was done with potassium chloride. But it was performed. And as I had mentioned and stated, I didn't see it with every testing certificate that was provided.

Q. It's your understanding that those tests that were performed were performed on CSPs and not final products for use by TDOC?

A. Well, the -- my understanding -- and I'm using CSP is the final product.

Q. You mentioned sterility, endotoxin, and potency. Do you see test results for any other quality requirements set forth in the USP?

A. Those are the three according to 797 which are required that the pharmacy send out prior to sending it to the end user.

Q. Do you know the methodology that the labs used to conduct each of those tests that you've seen results for?

A. The methodology they used, again, are in accordance with USP. So, for example, sterility is associated with USP 71; endotoxin, for the one certificate I did see it on, is in accordance with, if I recall correctly, USP 85; and the identification is an assay done by high-performance gas-liquid chromatography, which gets you a percentage. And the acceptable range, as I stated in my report, is plus or minus ten percent.

Q. I'm just pulling up a document. And you previously testified that you reviewed Dr. Almgren's report in this case; is that right?

A. I reviewed -- that's correct, I reviewed the first report and a rebuttal that was submitted, I thought around mid-January.

Q. And as you will recall, Dr. Almgren

identified a number of testing results that she believed were missing. Do you recall that?

A. I do, yes.

MR. SUTHERLAND: I'm going to object to the form and ask that you refer him to specific things in her report if you're going to talk about it.

MS. NELSON-MAJOR: I'm going to pull up Dr. Almgren's report. And we'll send a copy of that to you as well.

MR. SUTHERLAND: Thank you. Dr. Patel, I'll forward this to you as soon as I get it.

THE WITNESS: No problem.

MS. NELSON-MAJOR: I'm going to wait, instead of trying to get you to take a look at the screen, because the font is small on this document.

MS. LEONARD: I just e-mailed it. So hopefully it's not a long delay this time.

MR. SUTHERLAND: Just got it and I just forwarded it.

BY MS. NELSON-MAJOR:

Q. And while you're pulling that up, Dr. Patel, I'm just going to mark for the record Dr. Almgren's report as Exhibit 5.

A. Okay.
Q. And I'm looking at paragraph 35, which begins on pdf page 13, I believe.
A. One second. The pdf is still pulling up. Oh, shoot, I lost it. You said page 13?
Q. Paragraph 35 begins on page 13 of the pdf and then continues on to the next page. I'm sorry, begins on page 12 and continues on to page 13.
A. There we go. Okay. I have it.
Q. Okay.
A. Making it larger.
Q. So you reviewed this bulleted list in which Dr. Almgren reviews the available documentation of the test results that were performed on midazolam compounded for TDOC?
A. That's correct.
Q. And in each bullet point Dr. Almgren looks at a separate CSP compounded for TDOC and notes the test results that were reported on the documents; is that right?
A. That's correct.
Q. And you also reviewed the test results that were provided for the midazolam compounded for TDOC?
A. I have, yes.

Q. Dr. Almgren identifies a number of tests that were not performed on each one of these batches of midazolam compounded for TDOC. For example, I'm looking at the first bullet point, which is for a midazolam sample submitted on September 22 of 2018, there was an assay and sterility test reported, but no other test results were available. Do you see that?

A. The first one? Yes, I do.

Q. In your review of the records, did you see any other test results reported for that midazolam sample?

A. For that one? No, I did not.

Q. If you had compounded midazolam for patient use in a clinical setting and had only received an assay and a sterility test result, would you release that sample for use on a patient?

A. For the CSP? No, we would have to wait for endotoxin results to return.

Q. And if you then took this CSP and prepared it for final preparation and use on a patient, what other tests would you have to perform?

A. The only one is, as I had mentioned, is endotoxin. Again, that's testing for pieces of dead bacteria that can trigger a fever.

Q. You wouldn't test it for pH prior to patient release?

A. Prior to patient release it is not tested for pH. pH is tested prior to sending it for the sterility and potency evaluation.

Q. So this particular midazolam sample you would not release until it had been tested for pH and endotoxins in a clinical setting; is that right?

A. The pH is done prior to its being sent, so it's the last step in actual physical preparation. And, correct, the endotoxin would be due to the risk of fever, which, again, could be potentially present hours to days after administration. That's correct.

Q. And then I'm going to ask you to turn to paragraph 37 of Dr. Almgren's report. Excuse me, paragraph 38.

A. Okay.

Q. So as with midazolam, Dr. Almgren reviewed the records of test results performed on the potassium chloride compounded for TDOC. In your review of the records of the test results, did you see other results of testing performed on potassium chloride that Dr. Almgren failed to include in her report?

A. I have not, no.

MR. SUTHERLAND: Object to the form.

BY MS. NELSON-MAJOR:

Q. Looking at the second bullet point in paragraph 38, it states that potassium chloride received on August 6 of 2019 was tested for assay and failed with a potency of 94 percent. There was no indication that it had been tested for sterility.

In that case, would you have released that sample for patient use?

A. No. And it's not because it didn't pass potency. Right? Remember, potency is plus or minus ten percent. So it actually passes potency. But there is not a sterility or endotoxin testing and that's why it's actually failed.

Q. I want to ask you about that potency quality requirement in a moment, but just to close the loop on this. In your clinical practice, do you document the test results for the compounded preparations that you prepare?

A. No, there is no documentation, because your documentation is the analysis that was performed when it was sent out.

Q. By a lab?

A. That's correct, it would be an independent laboratory.

Q. Does the independent laboratory provide you with documentation of the test results?

A. That's correct. And that's what I believe we've been reviewing.

Q. And do you maintain records of those test results in any way in your pharmacy?

A. No. After they're verified and confirmed, they're not really of any -- of any need.

Q. I want to turn to your report again, and we're going to look at page 12. Let me know when you're there.

A. Okay.

Q. I'm looking at that first full paragraph again, the second sentence, which begins, "The accepted standard." Do you see where I am?

A. It's on page 12. And which paragraph and sentence are you referring to?

Q. The first full paragraph. It's the paragraph that begins, "The Pharmacist outlined."

A. I see that, yes.

Q. Okay. Now I'm looking at the second sentence, excuse me, which states, "The accepted standard by USP for label strength is within 10 percent and prepared to maintain sterility until the beyond use date. Meaning the acceptable potency is

between 90 [to] 110 percent."

Is the 90 to 110 percent that you identify there true for all compounded preparations?

A. That's correct, under the recommendations of USP.

Q. And the USP monograph for a particular drug doesn't set a separate potency standard?

A. That's incorrect. So, for example, if you pull up the monograph for USP in terms of the API, it's identical to the EP and BP. The plus or minus ten percent, so it's not confused, it applies to the finished CSP which was sent for testing. Those are two different things.

Q. The question I'm asking about is the CSP. Do the USP monographs for CSPs, or compounded preparations, vary from drug to drug?

A. I don't understand your question. The monograph applies to APIs. The standard for USP for compounded sterile preparation, or CSPs, is always plus or minus ten percent. So I don't understand the question, it doesn't make sense to me. I apologize.

Q. No, that's fair. I'm going to pull up another exhibit, and we'll e-mail that to you, it's a USP monograph for potassium chloride. And I'm

going to wait until you receive this, so you can read it more clearly.

MR. SUTHERLAND: I just forwarded it to you, Dr. Patel.

A. I got it. Okay. Thank you.

Q. Do you see at the top of this page it says, "Potassium Chloride for Injection Concentrate"?

A. I do, yes.

Q. Have you seen this document before?

A. I have, yes.

Q. And what is it?

A. This appears to be the copy that was printed in regards to potassium chloride concentrate in accordance with USP. It appears to be a monograph.

Q. And I'm looking at the paragraph right under the heading I just directed you to. Do you see where it states, "It contains not less than 95 percent and not more than 105 percent of the labeled amount of KCl"?

A. That's correct.

Q. Is that a potency requirement for potassium chloride for injection concentrate?

A. That would be the potency for a bulk

package, or API, that's correct.

Q. Excuse me, I'd like to mark this as Exhibit 6. I neglected to do that.

So does that mean when the potassium chloride is subjected to potency testing, that it needs to be within 95 and 105 percent of the labeled amount of KCl?

A. For potassium chloride, that's correct.

Q. And is that different than the 90 to 110 percent range you noted in your report?

A. That's correct.

Q. I'm going to pull up a test report for a batch of potassium chloride that was compounded for TDOC, and we'll e-mail this to you as well. I've also pulled it up on the screen.

MR. SUTHERLAND: I just got it and I'm forwarding it now.

Q. Do you have that document, Dr. Patel?

A. Yeah, it's pulling up. Give me just a second. Okay.

Q. Is this a document that you've previously reviewed?

A. If it was with the associated testing reports then, yes.

Q. It's a laboratory report for potassium

chloride and it has date received July 16, 2019. Do you see that?

A. I do, yes.

Q. I'm going to mark this as Exhibit 7. There's two test results reported on this document. What was the number reported for potency?

A. For this batch that was sent for testing, it was 112 percent.

Q. And what does 112 percent mean in this context?

A. It's 112 percent, 12 percent stronger than the 2 mil equivalent per mL.

Q. So this preparation does not meet the USP standards for potency for potassium chloride; is that right?

A. For testing, for the recommended 95 to 105 percent, that's correct, this would not pass.

Q. It also doesn't pass that other 90 to 110 percent range that you noted in your report; is that correct?

A. That's correct.

Q. If you received a report indicating that a drug had exceeded the acceptable potency range, would you release it for use?

A. For use in patient care, no.

Q. So we just looked at that USP monograph which states the acceptable range between 95 and 105 percent for potassium chloride. Why did you state that the acceptable range for both drugs was 98 to 110 percent in your report?

A. In clinical practice, plus or minus ten percent is virtually used for compounded medications. The USP has recommendations of a specific range for different chemicals or preparations that are compounded individually. And plus or minus ten percent is what is used clinically.

Q. And if the USP specifies a different range for a particular drug, do you follow that different range or do you follow the general range when compounding a preparation?

A. No, you would default to the USP recommendations in the setting of inpatient patient care.

Q. All right. I'm going to pull up a different test result report, and we'll e-mail that to you as well.

When you were drafting your report, did you consult the USP monographs for midazolam and potassium chloride?

A. Did I consult them? No. Did I review them? Yes.

MS. NELSON-MAJOR: Let me know when you've received that, Mr. Sutherland.

MR. SUTHERLAND: Just sent it.

MS. NELSON-MAJOR: Thank you.

THE WITNESS: Okay. I have it.

BY MS. NELSON-MAJOR:

Q. This is another lab report for potassium chloride, with a date received August 6, 2019. Is this a lab report that you've also reviewed before?

A. If it was within associated documents, that's correct.

Q. I'm going to mark this lab report as Exhibit 8. What is the potency result reported for this batch of potassium chloride compounded for TDOC?

A. It's 94 percent.

Q. And, again, what does 94 percent mean in this context?

A. Just as stated, instead of 2 mil equivalent per mL, it's 1.88 mil equivalent per mL.

Q. If you received this report for a batch of potassium chloride that you compounded, would you release it?

A. Since you default to 95 to 105, no, you would not, for patient care.

Q. I'm next going to pull up the USP monograph for midazolam. If you hang tight, we'll e-mail that to you as well.

MR. SUTHERLAND: On its way.

A. Okay.

Q. Have you seen this document before?

A. I have, yes.

Q. And what is it?

A. It's the associated monograph for midazolam.

Q. And there's -- I've highlighted a sentence in the first paragraph of the definition, which states, "It contains the equivalent of NLT" -- meaning, I'm assuming, not less than -- "90 percent and NMT" -- meaning not more than -- "110 percent of the labeled amount of midazolam."

Is that the acceptable potency range set for midazolam?

A. That's correct, it's plus or minus ten percent.

Q. I'm going to pull up a test result, and we'll e-mail that to you as well. Let me know when you receive that.

MR. SUTHERLAND: On its way.

MS. NELSON-MAJOR: Thank you.

A. Okay.

Q. And have you seen this lab report before?

A. If it was within the documents and what's cited, yes, I likely have.

Q. So it's a lab report for midazolam with a date received of November 13, 2019. I'm going to mark that as Exhibit 10.

And what is the potency result reported for this batch of midazolam?

A. The potency as stated as tested is 114 percent.

Q. Meaning it was 14 percent higher than the intended potency?

A. Four percent above the acceptable limit, that's correct.

Q. My question was, was it 14 percent of the intended volume of midazolam specified for this -- that was a terrible question, let me try restating that for you.

The potency measures the actual amount of midazolam in the compounded preparation versus the intended amount of midazolam; is that correct?

A. That's correct.

Q. And so this compounded preparation had 14 percent more midazolam than the target amount of midazolam the pharmacy intended; is that correct?

A. That's correct, a total of seven milligrams per mL more.

Q. So this compounded midazolam does not meet the acceptable potency range set by USP; is that right?

A. That's correct, it's four percent above.

Q. And if you had received this report for midazolam that you had compounded, would you have released it?

A. No, we would not have released it for patient care.

Q. You reviewed the deposition of the pharmacist who supplies TDOC with lethal injection drugs, correct?

A. I did review that deposition, that's correct.

Q. And so you're aware that the compounding pharmacy sent CSPs to a third-party lab for testing?

A. That was my understanding based on their standard operating procedure, that's correct.

Q. And you're also then aware that that third-party company had been issued a violation

letter by the FDA?

A. That they've been issued a violation letter by the FDA? No, I'm not familiar. But I'm also not surprised.

Q. So you don't recall that the pharmacist testified that the testing company that they had contracted with had been issued a violation letter?

A. No, I don't recall that exact sentence or that the pharmacist testified to that.

Q. Why do you say that you're not surprised?

A. For any that are in the healthcare, especially the compounding, industry are familiar with virtually any infraction, whether it would be during preparation, testing, or any part of the process, there is a subject and a risk of error or something going wrong. And so whether it's a small pharmacy or a large manufacturer; for example, Nephron, nobody's devoid of any infractions of citations. So I'm not surprised.

Q. So, in your opinion, have most third-party testing labs been issued FDA violation letters?

A. It's not that most have been issued, it's the fact that any person, whether it's a individual pharmacy or a large 503B manufacturer, at some point is going to have an infraction on the testing or

analysis or their policy and procedure once inspected.

So, no, I'm not surprised they've been issued an FDA letter. In fact, most of our 503Bs that are available to us here in the U.S., there's not a single one that I'm aware of that doesn't have an infraction letter, inclusive of Nephron.

Q. And I'm specifically asking about third-party testing companies, not 503B manufacturers. Would what you just stated also be true about third-party testing companies?

A. That's correct. But you have to recall, that in order to be subjected to a violation, they have to register and undergo an evaluation. So just because it's a third-party testing laboratory doesn't automatically assume they're always going to get inspected or when they do. So that's why I mention I'm not surprised.

Q. Do you know the nature of the violation that caused the FDA to issue the letter to the third-party testing company that the compounding pharmacy uses?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: I do not know the nature of the letter, nor have I seen it, no.

BY MS. NELSON-MAJOR:

Q. So you're not aware if it's a minor violation or something more serious?

A. No. But from my background, training and experience, if it's serious, that generally shuts down a facility or a company or a testing area for a prolonged period of time.

MS. NELSON-MAJOR: Mr. Sutherland, I'm at a good stopping point. I know that you had wanted to stop at this point, so maybe that makes sense.

MR. SUTHERLAND: Yeah, this is a good time. Maybe come back at 11:30, if it's all right. I'm sorry, 11:30 Central, 12:30 Eastern.

MS. NELSON-MAJOR: I understood you. Dr. Patel, does that work for you?

THE WITNESS: Yeah, that's fine for me, not a problem.

MS. NELSON-MAJOR: Okay.

MR. SUTHERLAND: Thank you very much.

VIDEOGRAPHER: Going off the record, the time is 10:58.

(A brief recess was taken.)

VIDEOGRAPHER: Back on the record, the

time is 11:31.

BY MS. NELSON-MAJOR:

Q. Dr. Patel, did you talk to anyone during that break?

A. No, I did not.

Q. I'm going to direct you back to your report, page 12, if you want to pull it up.

A. Okay.

Q. I'm looking at the paragraph on the bottom of the page, which starts, "Once the pharmacy is ready to ship the CSPs (midazolam and potassium chloride) and vecuronium it is packaged in dry ice with a temperature gauge device to facilitate safe transport..."

Are all three of the drugs to be shipped on dry ice?

A. No, the vecuronium is room temp, the midaz and potassium chloride is dry ice.

Q. And what is the temperature gauge device that you reference?

A. If I recall correctly, the pharmacist described -- and there's a number of proprietary products. But if I recall correctly, it was a mechanism which had a blue dot to signify that the packaging box in itself was within range during

transport.

Q. And how does that temperature gauge device facilitate safe transport of the LIC to TDOC?

A. It's pretty standard operating procedure that if you receive it from anybody preparing CSPs, that there is a mechanism of some sort, because the -- one of the most important things is the temperature during transport.

Q. What would happen if the recipient was unaware that the package contained a temperature gauge device?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: If the recipient is unaware that a temperature gauge device?

MS. NELSON-MAJOR: Uh-huh. That was my question.

THE WITNESS: Well, if there wasn't a temperature gauge device, then they wouldn't know, for example, for CSPs that require either a refrigerator, or in this case a freezer, if it was within range during transport.

BY MS. NELSON-MAJOR:

Q. And you reviewed the deposition of the

drug procurer. That's correct?

A. That is correct, yes.

Q. And so you're aware that, according to the drug procurer, the dry ice shipments from the pharmacy do not contain a temperature gauge device?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: Based on what the pharmacist, I believe, testified to, and I believe that it was labeled pharmacy owner, that is their standard procedure for shipping CSPs that are frozen.

BY MS. NELSON-MAJOR:

Q. And from reviewing the drug procurer's deposition, you're aware that the drug procurer is the person who receives the drugs at TDOC?

A. That is my understanding, yes.

Q. And if the drug procurer is unaware that there's a temperature gauge device in the box, is the drug procurer able to assess whether the temperature went out of range during shipment?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: If that mechanism or device the pharmacist and pharmacy owner had

described was not in place then, no, the drug procurer would not know that.

BY MS. NELSON-MAJOR:

Q. And in that case, obviously, the temperature gauge device couldn't ensure safe transport of the LIC to TDOC, correct?

A. As for the required temperature, that's correct.

Q. And then continuing on onto page 13 of your report, you note that TDOC stores the LIC in a fridge/freezer that has a temperature probe monitor on the outside to "track the temperature." What do you mean by "track the temperature"?

A. It's a monitor that tells you what the temperature is inside the container.

Q. Does the probe send an alert if the temperature goes above or below a certain range?

A. Not to my knowledge, no. Nor is it required.

Q. Does it record the temperature at a given interval?

A. From my understanding and review of the records, no. Nor is it required.

Q. And what do you mean when you say, "Nor is it required"?

A. Just as I stated, if you go to USP page 29, it'll actually identify the requirements for the recipient. In this case, that would be TDOC.

MS. NELSON-MAJOR: I'm going to pull up a document that we will -- I believe was already sent to you over the break, Mr. Sutherland, some photographs. And I'm also pulling them up on my screen.

MR. SUTHERLAND: I just forwarded them.

THE WITNESS: Okay.

BY MS. NELSON-MAJOR:

Q. Are these the photographs that you cited in your report of the fridge and freezer?

A. I believe these are it, yes.

Q. I'm going to mark these photographs as Exhibit 11. Does this mini fridge have a separate freezer and refrigerator compartment?

A. From my -- from looking at the photograph, my understanding, yes, the top was the freezer and the bottom's the fridge.

Q. And in your report you note that the compounded preparations are stored in the freezer but are later moved to the fridge to thaw prior to an execution. Is that your understanding?

MR. SUTHERLAND: Ms. Nelson-Major, when

you refer to his report, will you please direct him to where you're talking about, just so there's no misunderstanding? I'm sorry.

Q. So, Dr. Patel, we're still on page 13, still on that paragraph that I pointed you to, and you write, "Once received by TDOC, the LICs are stored in a separate building, secured via a steel lock on the fridge and freezer..."

And then scrolling down to page 13, the first full paragraph, the first sentence, you write, "Once TDOC is ready to administer the LIC, the CSPs are removed from the freezer (negative 25 degrees to negative 10 degrees C) and placed into the refrigerator as instructed to allow the medication to thaw.

And in this paragraph of your report you reference a temperature range for the freezer and refrigerator. What are those temperature ranges?

A. They're the ones in the report.

Q. And what are those temperature ranges?

A. For the freezer it's a range of minus 25 to minus 10, and in the fridge it's 2 to 8 centigrade.

Q. And where do you get these temperature ranges from?

A. A couple of places. One is my house and the second is USP.

Q. What do you mean you got those temperature ranges from your house?

A. That's what the manual says on the fridge.

Q. So these temperature ranges, are you citing the manual for your fridge at your house or the USP guidance for storage?

A. They're two of the same.

Q. Turning back to Exhibit 11, the pictures of the fridge. Did you see the manual for this mini refrigerator in discovery?

A. Did I see the manual? No, I didn't see the actual manual. I see it's Frigidaire, in terms of the brand.

Q. So you don't know whether this fridge has the same temperature ranges as your refrigerator at home?

A. No, I don't know if it's the exact same range. But the probe on the outside tells us.

Q. And taking a look at the probe on the outside, have you seen this type of probe before?

A. Have I seen that type of probe? No, I've never seen that type of probe before.

Q. Does the temperature monitor on the

outside of this refrigerator read the temperature in the fridge compartment or the freezer compartment?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: Sure. My understanding is, it's reading the refrigerator compartment.

BY MS. NELSON-MAJOR:

Q. And why is that your understanding?

A. Based on the temperature that's listed there in centigrade. Or, I'm sorry, in Fahrenheit.

Q. And what is the temperature that's listed?

A. I thought it was 36.9 or -- if I remember right.

Q. I'm going to scroll to the second page, where there's a closer view of the monitor. And what about the fact that it's 39-- excuse me, 36.9 Fahrenheit leads you to believe that the temperature probe is in the fridge compartment?

A. Because if you equate that to Celsius, it would fall within range, if I remember right.

Q. And what is 36.9 in Celsius?

A. I can do the calculation. I didn't do it off the top of my head.

Q. No, Dr. Patel, that's fine, I'm not asking you to do the calculation. It sounded like at one

point you perhaps had done the calculation and that's why I was asking.

Do you see in the bottom left corner of the monitor there's a large X?

A. Yes.

Q. And on the yellow perimeter of the monitor below that large X, do you see where it says, "Alarm state"?

A. I do, yes.

Q. And then below "Alarm state" there is a checkmark with an equals sign to "OK"?

A. That's correct.

Q. And then below that there's a large X with an equals sign to the word "ALARM"?

A. That's correct.

Q. Does the X on the screen indicate that the temperature readings have triggered some sort of alarm?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: If it triggered an alarm? Well, it looks like it's an X. But I don't know if that's because a picture was taken or if it triggered an alarm. So I actually can't say.

BY MS. NELSON-MAJOR:

Q. Do you know what range TDOC sets that monitor to as far as temperature?

A. Do I know what range it set it to?

Q. Yes.

A. No, I can't tell by looking at this. No.

Q. And at the top of the monitor, do you see a series of triangles?

A. I do, yes.

Q. And above that series of triangles on the perimeter of the monitor there's a series of striped markings?

A. If you're referring to the triangles, yes.

Q. And the first striped marking starting from the right-hand corner says, "today." Do you see that?

A. That's correct.

Q. And then the next striped marking says, "yesterday"?

A. That's correct.

Q. And then the next one says, "minus 2d"?

A. Correct.

Q. Does it appear that "minus 2d" means two days ago, given the sequence?

MR. SUTHERLAND: Object to the form.

You can answer, if you know.

THE WITNESS: I don't know, no.

BY MS. NELSON-MAJOR:

Q. Do you see that after minus 2d, it goes minus 3d, minus 4d, minus 5d, all the way up to minus 29d?

A. That's correct. I see that.

Q. Are you aware that each triangle indicates that the probe recorded a temperature outside of a specified range on the day indicated on the striped marking on the perimeter?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: No, I'm not aware of that. No.

BY MS. NELSON-MAJOR:

Q. And you weren't provided with a copy of the user manual for this temperature probe, were you?

A. I do not have a --

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: Oh, sorry. No, I don't have a manual, so I can't comment.

BY MS. NELSON-MAJOR:

Q. How often does TDOC check the temperature gauge?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: How often do they check the temperature gauge that's storing the LICs?

MS. NELSON-MAJOR: Correct.

THE WITNESS: I don't know how often they check it.

BY MS. NELSON-MAJOR:

Q. Do you know when TDOC installed this temperature gauge?

A. I do not know, no.

Q. Do you know what action TDOC would take if an alert was sounded on the temperature gauge?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: I do not know, no.

BY MS. NELSON-MAJOR:

Q. I'm going to turn back to your report, if you could pull that up, please.

A. Okay.

Q. And I'm going to ask you to look at page three.

A. Okay.

Q. And I'm looking at the heading: Materials Reviewed and Relied Upon. Why didn't you include the photographs of the mini fridge on this list?

A. Why didn't I include them? Because they were one of the produced exhibits. But I cited it. So I guess I don't understand. Why isn't it listed twice is what you're asking?

Q. No, I'm asking you why these documents -- these photographs don't appear on this list.

A. Oh, I see what you're saying. I felt it was redundant. So I cited it within the report, which it should be.

Q. Are there other documents that you reviewed and relied upon but didn't either cite in section three or elsewhere in the report?

A. If it's cited, then if it's not in that section three, then I would imagine it probably is, I don't know. I just felt it was redundant, so I didn't include it in two places.

Q. I don't think my question was clear. Let me try again. So you're saying every document that you have reviewed and relied upon is either cited in this section or in the body of your report; is that right?

A. Affirmative.
Q. Are there other documents that are not cited in this section or the body of your report that you reviewed and relied upon?
A. I don't believe so. They should all be contained within the report, unless they were materials I was provided, like I mentioned in the beginning, thereafter.
Q. Did you read the deposition of the executioner?
A. I did, yes.
Q. Are you aware that when asked to describe how he follows aseptic techniques when preparing the syringes, the executioner said that he cleans the needle with an alcohol wipe? Do you recall reading that?
A. I recall that, that's correct.
Q. Is wiping the needle with an alcohol wipe consistent with aseptic technique?
A. It is not consistent with aseptic technique within a patient care setting.
Q. Does aseptic technique vary based on the setting in which the procedure is being performed?
A. According to the recommendations, aseptic technique was originally asserted and defined in the

setting of diagnosis, care, treatment, and healing. So, yes, it does vary.

Q. Is your --

A. Different? Yes, it is different than what is recommended.

Q. And, I'm sorry, Dr. Patel, I thought you were pausing because you were finished. My apologies.

Is it your opinion that the aseptic technique that the protocol requires TDOC to follow during an execution is different than standard aseptic technique in a clinical setting?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: For the purposes of the end user, they followed the instructions as provided by the pharmacy. Is using a alcohol swab on a needle different than what's recommended, that's correct. Does it introduce a risk that is subjected, that's correct, and I believe it's negligible. But it is different, that is correct.

BY MS. NELSON-MAJOR:

Q. Is the needle sterile before it is taken out of the package?

A. The needle is sterile.

Q. And does touching the needle mean that it is no longer sterile?

A. That's incorrect. Touching the needle with your bare hands is the issue. If I recall correctly, the executioner described putting on gloves and then, if I remember right, swabbing the tip of the needle with the alcohol swab, which is not recommended.

Q. If a compounded preparation is drawn up into a syringe in a non-sterile environment, how soon must it be administered?

A. In the setting of diagnosis, care, treatment, and healing it would be within one hour.

Q. And the caveat you gave to that answer is in a diagnostic setting, clinical setting. Are you suggesting that those standards don't apply in this context?

A. Those are standards set forth by recommendations by the USP and enforced by the FDA, which means it has to be applicable in the setting I just mentioned, which would be diagnosis, care, treatment, and healing, or in some cases a patient's home. This is none of the above.

Q. And so, in your opinion, because this is

neither a patient's home or a clinical setting, those standards do not apply?

A. No, my opinion is, is that the recommendation is within one hour. However, it's important to remember why that is the recommendation. And the risk is predominantly sterility, which is not an issue here as the impact of that is hours to days after drug administration. But that's why -- I'm explaining that's why that's my opinion.

Q. If a compounded preparation is not drawn up -- excuse me, if a compounded preparation is drawn up in a non-sterile environment and it's not administered within one hour, does the risk of precipitation increase?

A. Is that a general question, I'm sorry, or specific to one of the LICs?

Q. I'm asking as a general pharmacological principle about compounded preparations. Is the concern about precipitation one of the reasons why the USP requires a compounded preparation to be administered within one hour if drawn up in a non-sterile environment?

A. That's actually one -- that is actually compounded or CSP specific, it's not applicable to

all. Because if your medication is in solution already, it's irrelevant.

Q. What about a solution made from a reconstituted powder; such as, vecuronium bromide?

A. Again, it'd be irrelevant, based on the references I've already provided. Vecuronium is stable with sterile water for 24 hours at room temp and bacteriostatic water for five days. So whether it's used within an hour or not is irrelevant. But that's why.

Q. So under the USP, vecuronium bromide that is reconstituted in a non-sterile environment does not need to be administered within one hour?

A. That is a hundred percent correct, because you have scientific literature and data that prove otherwise.

Q. And that's what the USP requires?

A. Correct. Which goes a hundred percent against what the manufacturer requires. So you actually go to the manufacturer, because they're the ones that made the drug.

Q. And under USP 797, if a drug is drawn up in a syringe in a non-sterile environment and not administered within one hour, is it considered expired?

A. In the setting of diagnosis, care, treatment, and healing, that is correct.

Q. And is that preparation then considered an immediate use compounded sterile product?

A. These are immediate use preparations, that's correct.

Q. Were you asked to give an opinion on what portions of the USP should -- or do apply to the execution context?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: Well, I think I've already been opining. If we read the TDOC manual, I thought it was page 35, it's pretty clear, the USP is applicable to the pharmacist and pharmacy preparing, testing, and sending the LIC, it is not applicable to the person diluting and administering it, as outlined, because the TDOC is not regulated nor reviewed by USP or the FDA, that I'm aware of.

BY MS. NELSON-MAJOR:

Q. Is reconstituting a powder drug into a solution for injection considered compounding?

A. That's correct. It would be applicable in the patient care seating, in a hospital, or a

patient's home.

Q. I want to turn your attention back to the protocol, and I'm looking at page 34.

MR. SUTHERLAND: I'm sorry, Ms. Nelson-Major, where are you?

Q. I'm looking at the protocol, introduced as Exhibit 2, page 34.

A. Okay.

Q. You just testified that it was your reading of the protocol that the USP standards that the protocol references only apply to the compounding pharmacy. And I want you to clarify for me where in the protocol you see that limitation.

A. Sure. In the paragraph it says very clearly, "Chemicals used in lethal injection executions will either be FDA-approved commercially manufactured drugs; or, compounded preparations prepared in compliance with pharmaceutical standards consistent with the United States Pharmacopeia and accreditation Departments, and in accordance with applicable licensing regulations."

Nowhere in that paragraph does it state TDOC, nor is it a standard, is held to USP regulatory requirements -- well, they're not actually regulatory requirements, they're

recommendations, when diluting, administering, preparing, storing the LIC. But it's continued on page 35, if you want me to go to it.

Q. That is the only question I had about that portion. I'm going to take down -- I'm not sharing my screen anymore.

Are you aware that TDOC prepared the syringes of vecuronium bromide and potassium chloride two hours prior to administering the drugs to both Donnie Johnson and Billy Ray Irick, the two men executed under this protocol?

A. From my review of the records, that's correct.

Q. And assuming USP 797 applies, the second and third drugs TDOC used to execute Mr. Irick and Mr. Johnson were expired under the USP; is that correct?

A. Under that hypothetical --

MR. SUTHERLAND: Excuse me. Object to the form. You can answer.

THE WITNESS: Sorry. Under that hypothetical, that would be correct.

BY MS. NELSON-MAJOR:

Q. I'm going to return you back to your report, on page 13. I'm looking at the second full

paragraph, which begins, "The inmate is prepared for lethal injection by first obtaining intravenous (IV) access." Do you see that?

A. I do. That's correct.

Q. And in this paragraph you summarize what the protocol says about establishing IV access?

A. That's correct.

Q. Have you ever obtained IV access on a patient?

A. Have I physically obtained IV access on a patient? No.

Q. Is that something you were trained to do?

A. Trained to establish IV access? No. Trained to evaluate it? Yes.

Q. And where did you receive IV training?

A. During residency and observation during the last 20 years of my career directly with humans, patients.

Q. Are you offering an opinion on the procedures the execution team uses to establish IV access?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: No, other than what I've stated, which is it's an antecubital fossa,

which if you're familiar, it's the large vein in the inner elbow which is utilized, an 18-gauge needle is what they utilize, which is fairly large, and that minimizes any irritation, whether it's from saline or any other drug. Oh, sorry. Go ahead.

MS. NELSON-MAJOR: No, please finish your answer.

THE WITNESS: Notably, it's placed by EMTs. And so if you're familiar with EMTs in the field, the field where they present to somebody's home or to a gunshot wound victim, is not a sterile area, they're placing these there.

The reason I mention that is you keep mentioning USP. Well, any medication EMTs are drawing up in the field and administering are not discarded in an hour, and that's clearly a patient care setting. So that would mean every EMS and EMT in the country is violating that standard. So that's why I'm saying it doesn't apply here.

BY MS. NELSON-MAJOR:

Q. And do EMTs routinely draw up medications into syringes prior to administration and then wait

to administer them? Is that what you're saying?

A. Negative. You keep mentioning the expiration time. And what I'm mentioning and clearly stating, in real life or clinical practice, drawing up and administering within an hour, even for an EMT that's going en route, the drug is not discarded. They're drawing it up because they need it or might need to administer it. They don't throw everything out after one hour and draw everything up again.

So I'm stating there are clearly exceptions even in a patient care setting where USP as a recommendation says, yeah, draw it up into a syringe and toss it out after 59.9 minutes, and what I'm clearly stating is that's not true nor the reality.

Q. And in your clinical practice, how often do you draw up medications more than an hour in advance of them being administered to a patient?

A. We're preparing them for providers, so they're already drawn up in a hood. But from my observation, yes, things are drawn up in advance; for example, in an organ transplant case, where they may not necessarily be discarded exactly at the 61-minute mark. That's all I'm stating.

Q. And you stated that when you draw them up

in a syringe, it's done in a hood; is that correct?

A. That's correct, unless it was an emergency. For the setting of diagnosis, treatment, care, and healing.

Q. And why in a non-emergency situation are those drugs drawn up in a hood?

A. The main reason is actually sterility. So there is a possibility of infection or in some case a pyrogenic response, which is a fever, which could be noted hours to days after administration. That is the main reason.

Q. The next paragraph on your report on page 13 states, "Standards for point of care use by patients are similar to those demonstrated and used at an execution."

What standards are you referring to here?

A. It would be the ones outlined on USP, as I stated on page 29. The responsibility after leaving the pharmacy is upon the recipient, with the instructions provided.

Q. Then you state, "The pharmacy provides detailed instructions for drug storage, supplies required for reconstitution, and reconstitution of the medication prior to administration."

Have you seen the instructions that the

pharmacy provides to TDOC for reconstituting the vecuronium bromide?

A. No. Those are followed in accordance with the package insert that comes with every single vial, because it's manufactured, not produced as a CSP.

Q. Can you give an example of how a patient may compound a sterile preparation within their own home?

A. Sure. It would be exactly outlined as described in the instructions from the pharmacy for either midazolam or potassium chloride. Instructions meaning, in general, how it should be stored, how it should be reconstituted, and a procedure for drawing out the medicine.

Q. Is it your opinion that the level of instruction and precaution required to carry out an execution need only be equivalent to the level of instruction, precaution that a patient uses at home when dealing with a CSP?

MR. SUTHERLAND: Objection to the form. You can answer.

THE WITNESS: That's correct, for the lay public. I believe the instructions provided were detailed enough for a layperson

to follow.

BY MS. NELSON-MAJOR:

Q. I'm going to direct you to page four of your report.

A. Okay.

Q. Do you see the section titled: Consciousness check?

A. I do, yes.

Q. Are you offering an opinion on the adequacy of the consciousness check in TDOC's protocol?

A. I don't perform consciousness check. No. But my main purpose of putting that in there is outlining TDOC's protocol, which if you carefully review it, actually mimics about a half a dozen of the studies referenced in the different reports on the Plaintiff side.

Q. So you're not offering an opinion on the adequacy of the consciousness check?

A. No, just that it's the same as what they used when they were studying midazolam in those scenarios, it's almost verbatim.

Q. And in those studies that you're referencing, what was the noxious stimuli or other stimuli that was administered to those patients?

A. Well, that's in the setting which you have to clearly define is in research, which means first we have to get patient consent, and it's in the setting of diagnosis, treatment, care or healing. And in that setting, the patients again consent to the study, and the investigators did the exact same protocol that's outlined almost verbatim there.

Q. And what level of sedation were those studies assessing?

A. They were assessing therapeutic dosing of midazolam.

Q. And in those studies were the patients given a stimulus after administration of the midazolam?

MR. SUTHERLAND: I'm going to object to the form.

THE WITNESS: It would depend on the study and how it was actually presented. Some refer to actual surgery, if I recall correctly, some refer to additions of either an inhaled anesthetic gas, if I remember right, and others had an intravenous opioid.

So, again, it's not the same thing we're talking about because none of them utilized 500 milligrams of midazolam. But the

consciousness check was exactly the same, that was my point, for a therapeutic dose.

BY MS. NELSON-MAJOR:

Q. And as part of your clinical duties, how often do you personally assess a patient's consciousness?

A. Oh, I already told you, I don't --

MR. SUTHERLAND: Object to the form. Object to the form. You can answer.

THE WITNESS: Sorry about that. No, I don't assess consciousness checks. I've already stated that.

BY MS. NELSON-MAJOR:

Q. And what does consciousness mean?

A. My opinion and my --

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: It would be awareness.

BY MS. NELSON-MAJOR:

Q. You said in your opinion. Where does that definition come from?

A. Consciousness? That's my understanding as a clinician working the last 20 years in a hospital.

Q. If a person is unconscious, can they feel pain?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: They can feel pain. However, the difference is, and the question is, can they experience pain.

BY MS. NELSON-MAJOR:

Q. Well, my question was, if a person is unconscious, can they feel pain?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: I don't recall if they can feel pain. My experience and the way I always understood it is if they can experience pain.

BY MS. NELSON-MAJOR:

Q. If a person is unconscious, can they respond to someone saying their name?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: According to the studies, they did not respond to verbal stimuli.

BY MS. NELSON-MAJOR:

Q. I'm asking a more general question about the parameters of consciousness, not the particular midazolam studies you're referencing. But if a

person is unconscious, as a general matter, can they respond to someone saying their name?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: Based on my understanding, I don't believe so, no.

BY MS. NELSON-MAJOR:

Q. And you were distinguishing between feeling pain and experiencing pain. If a person is unconscious, can they experience pain?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: In the setting of 500 milligrams of intravenous midazolam, no.

BY MS. NELSON-MAJOR:

Q. I'm asking a general question about the parameters of consciousness, unconscious versus conscious. If a person is unconscious, can they purposely respond to repeated or painful stimulation?

MR. SUTHERLAND: Same objection.

THE WITNESS: I don't have an opinion.

BY MS. NELSON-MAJOR:

Q. And when you say you don't have an opinion, is that because you don't know the answer

or because you just don't have an opinion? Like, can you explain that?

MR. SUTHERLAND: Object to the form.

THE WITNESS: Go ahead.

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: No, I just don't have an opinion.

BY MS. NELSON-MAJOR:

Q. Have you not thought about that question before?

A. No, I have not thought of that question. That's why I don't have an opinion.

Q. Is an unconscious person raiseable to painful stimulus?

MR. SUTHERLAND: Object to the form.

THE WITNESS: My understanding is, they would not be, no.

BY MS. NELSON-MAJOR:

Q. And are you aware that the American Society of Anesthesiologists have defined levels of sedation on a continuum?

A. I'm aware of that in the setting of surgery, yes, that's correct.

Q. And you earlier stated that you don't have

an opinion of whether -- if a person is unconscious, can they purposely respond to repeated or painful stimulus. Do you have an opinion in terms of the midazolam dose in this case, whether that would be sufficient?

MR. SUTHERLAND: Object to the form.

THE WITNESS: A 500-milligram intravenous dose of midazolam given 250 milligrams at a time, after waiting two minutes, yeah, I would believe the patient would be unconscious, it's my opinion.

BY MS. NELSON-MAJOR:

Q. All right. I'm going to pull up the American Society of Anesthesiologists chart that we were just talking about.

MR. SUTHERLAND: I just received it. And, Dr. Patel, it is on its way.

A. Okay.

Q. You testified that you're aware that the ASA has offered definitions of sedation, levels of sedation in the surgery context. Have you seen this chart before?

A. No, I have not. I'm aware the ASA has levels. But I'm not an anesthesiologist. I don't know the chart.

Q. Do you see at the top of the chart that there's four categories listed, beginning with, "Minimal Sedation Anxiolysis"?

A. I see that, yes.

Q. And then it progresses to "Moderate Sedation/Analgesia"?

A. I see that, yes.

Q. Then it progresses to "Deep Sedation/Analgesia"?

A. That's correct.

Q. And then the last category is "General Anesthesia."

A. Yes, I see that.

Q. And there's a corresponding level of responsiveness for each of those categories.

A. Okay.

Q. So what level of sedation on this chart corresponds to your definition of unconsciousness?

MR. SUTHERLAND: Object to the form.

THE WITNESS: Well, I never said any of them correlate to this chart, because I'm not an anesthesiologist. So I don't use this chart.

BY MS. NELSON-MAJOR:

Q. When you were employed by Rush Medical

Center, were you a professor?

A. I was -- that's correct. It's an associate professor.

Q. And what departments were you an associate professor in?

A. Within pulmonary critical care and anesthesiology.

Q. And in your duties as an associate professor in anesthesiology, did you ever consult this chart?

A. No. I taught about medications.

Q. So elsewhere in your report -- on page one, if you'd like to pull that up.

A. Sure.

Q. I'm looking at the last paragraph in the Introduction section. And you write that the inmate will be insensate during the transition to death. Do you see that?

A. That's correct.

Q. Is unconscious the same thing as being insensate?

MR. SUTHERLAND: Object to the form.

THE WITNESS: My understanding of insensate is, unconscious and unable to respond to physical stimuli.

BY MS. NELSON-MAJOR:

Q. And then on page five of your report -- I'm turning to the -- page five. There's a section entitled: Contingency provision.

A. Okay.

Q. And in here -- in this paragraph you write if the inmate is still conscious following the consciousness check, two additional syringes of midazolam 250 milligrams per syringe are already prepared and ready to be administered to the inmate.

Is it your belief that all of the midazolam syringes are prepared prior to the execution commencing?

MR. SUTHERLAND: Ms. Nelson-Major, I'm sorry, where are you referring to, where are you?

MS. NELSON-MAJOR: There's a paragraph with a heading titled "Contingency provision" on page five.

MR. SUTHERLAND: Okay.

BY MS. NELSON-MAJOR:

Q. And my question, Dr. Patel, is: Is it your belief that all of the midazolam syringes are prepared prior to the execution commencing?

A. My understanding is, the syringes, again

tagged red and blue, are prepared prior. Contingency, if I recall correctly, were the blue ones, which would be inclusive of this midazolam. That was my understanding from reading the protocol. Or manual, rather.

Q. And you write that following administration of the two additional syringes, the warden conducts another consciousness check before proceeding with the second and third drugs.

Does the protocol say what happens if the inmate responds to the consciousness check after administration of the second or backup set of midazolam syringes?

A. I don't recall, no.

Q. Moving on to the section below entitled: Drugs & Their Effects. What class of drugs does midazolam fall within?

A. The class -- you mean the drug class itself? It's benzodiazepines.

Q. And in your report you describe midazolam as a sedative-hypnotic. What does sedative-hypnotic mean?

A. As it states, the drug is sedating and/or can transition to hypnosis depending on, again, the benzodiazepine administered, the dose administered,

and the route administered.

Q. And what does hypnosis mean in a pharmacologic sense?

A. In my understanding and defining this for lay public and for students is, they are unaware of their surroundings.

Q. Are all benzodiazepines sedative-hypnotics?

A. They are in a class known as sedative-hypnotics, all of them, from my understanding, yes. But the reason is, is because sedative and hypnotic, you have to understand, is a transition. Something can be sedative and not hypnotic, but it's a progression forward.

Q. And are there other types of drugs besides benzodiazepines that are sedative-hypnotics?

A. Depending on the medication, the dose, and the route of administration, yes, there can be other classes. The only other one I'm aware of that can be classified as such are particular barbiturates.

Q. And later in that paragraph you write that the drug class of sedative-hypnotics is "designed to suppress the central nervous system (brain), resulting in a significant depressed level of consciousness and awareness."

What is the significance --

MR. SUTHERLAND: I'm sorry, Ms. Nelson-Major, where are you?

MS. NELSON-MAJOR: The same paragraph, the next sentence.

MR. SUTHERLAND: What paragraph? On what page?

MS. NELSON-MAJOR: We're still on page five, "Drugs & Their Effects," still under midazolam, the second sentence under the subheading "Midazolam."

MR. SUTHERLAND: Thank you.

BY MS. NELSON-MAJOR:

Q. So my question is, what do you mean by "significant depressed level of consciousness and awareness"?

A. As it states, midazolam is a fairly fast-acting benzodiazepine based on its properties, and so it does cause significant depressed levels of consciousness and awareness, which is why it's utilized as a pre-anesthetic medication or an induction anesthesia.

Q. Is that true regardless of the dose at which it is administered?

A. That's not a hundred percent correct. So

in a therapeutic setting, again, in the setting of diagnosis, care, treatment, and healing, it would be either one milligram, two milligrams, or five milligrams. In a pre-induction dose, for example in rapid sequence intubation, it could be upwards of 0.4 to 0.6 milligram per kilogram. So the escalation of the dose correlates with the depressed level of consciousness and awareness.

Q. And starting on the bottom of page five into page six, you discuss midazolam's mechanism of action. What does that term, "mechanism of action," mean?

A. How I would describe it to students or the lay public is, it's how in essence the drug works or its effects on the brain.

Q. And what is midazolam's mechanism of action?

A. Its mechanism of action falls into a series of steps. Meaning, if you go to that figure which is below, it first binds to the gamma-aminobutyric, or GABA, G-A-B-A, receptor. After the drug of the benzodiazepine class but specifically midazolam binds, it causes GABA to bind to the receptor itself, causing then an influx of what you'll see there, that chloride ion.

After -- and as it moves through that channel it causes a hyper-excitation which then nullifies any signal transmission, in this case awareness and consciousness, which is a layman's term for neuronal transmission in the brain.

Q. Can midazolam exert an effect on the GABA receptor if GABA is not present?

A. My understanding is, midazolam and benzodiazepines require gamma-aminobutyric acid, the most abundant amino acid in the brain.

Q. So at the bottom of the page, below that diagram you just referenced, you write, "Once the GABA binds to the GABA receptor the result is inhibition of brain neuronal activity; otherwise described as a loss of consciousness and awareness."

Are you saying that once any amount of GABA binds to a GABA receptor a person will lose consciousness?

A. At a therapeutic dose, that occurs. At a dose that we're discussing of 500 milligrams intravenously given 250 milligrams apart will certainly do that. Yes, that's what I'm saying.

Q. I'm asking as a general principle of midazolam's mechanism of action.

MR. SUTHERLAND: Object to the form.

THE WITNESS: That's correct, the therapeutic dose would cause that.

BY MS. NELSON-MAJOR:

Q. What does "ceiling effect" mean in pharmacological terms?

A. Ceiling effect is kind of a layman's way of understanding. And why they calling it ceiling; for example, the ceiling in your home is when you go past a certain -- you can't go past a certain threshold to not get clinical effect.

Q. So greater doses do not produce greater pharmacological effects above a maximum dose? Is that a fair way of putting it?

A. Generally, it's discussed and understood as a plateau, that's correct.

Q. In your opinion, does midazolam have a ceiling effect?

A. My opinion is, medications and drugs used in specifically the central nervous system do have a ceiling effect. However, I'm not aware of what the ceiling dose is for midazolam.

Q. So you're not aware of the dose; but, in your opinion, the ceiling does exist for midazolam?

A. The concept and the principle exist, that's correct. I'm not aware of what dose that

occurs at, no.

Q. And does a ceiling effect for midazolam exist because the body supply of GABA is limited?

A. It's not necessarily that the supply of GABA is limited. It's based on its mechanism of action where it is dependent on GABA and the binding. However, other medications that work in the central nervous system, or brain, have other mechanisms to cause unconsciousness that midazolam does not possess.

Q. And what are those other drugs that you're referencing there?

A. The drugs that have other ways of activating the GABA receptor; for example, could be the barbiturates is one example.

Q. And do barbiturates have a different mechanism of action than benzodiazepines?

A. They are very similar, with only one distinction.

Q. And what's that distinction?

A. They can cause the hyperpolarization with the presence of GABA and without the presence of GABA, as described on the diagram above.

Q. And do barbiturates also block exi-- I can never say this word, so I apologize. Do they also

block the excitation, excuse me, of neurons at glutamate receptors?

A. That's correct. That can be one of their mechanisms, in addition to other anesthetics.

Q. Does midazolam block excitation of neurons at glutamate receptors?

A. Not that I'm aware of, no.

Q. And you just mentioned that figure on page six. Why are the barbiturates depicted at a different place on the GABA receptor than the benzodiazepines?

A. I guess I don't understand the question. Why are they there instead of exactly where the benzodiazepines are?

Q. Is there significance to the fact that the barbiturates are depicted lower down on the GABA receptor than the benzodiazepines?

A. That is their associated binding spot and which is dual and can cause the chloride flux for hyperpolarization, as I describe. They're just different binding sites on the same receptor.

Q. And to be clear, barbiturates can work independently of GABA; is that correct?

A. That's a correct statement.

Q. And does that mean that barbiturates can

produce greater levels of central nervous system depression than benzodiazepines?

A. Depending on the dose and the route of administration and the particular barbiturate, that's correct.

Q. Scrolling down to page 15 of your report. And I'm looking at the first full sentence at the top of page 15 where you write, "Midazolam has been demonstrated to effect experiences of pain in a dose-dependent fashion." And then you have an endnote citation, number 29.

And at endnote 29 you cite an article entitled: "Neuropsychopharmacological effects of midazolam on the human brain," by Wang, et al.; is that right?

A. That's correct.

Q. I want to ask you a couple of questions about the article.

A. Sure. Could you just -- would you be able to send it real quick? That's all.

Q. Yes, I can do that.

A. Thank you.

MR. SUTHERLAND: Still waiting on it. I'm still waiting.

MS. LEONARD: I sent it about three

minutes ago. I'm not sure what the delay is, unfortunately. But, hopefully, it's going to get through to you soon.

BY MS. NELSON-MAJOR:

Q. Dr. Patel, I have a couple more general questions about this article. We could see if we could answer those, and then hopefully the document will come in. But if you feel like you can't answer any of those questions without seeing a copy of the article, we can pause and wait for it to arrive. Does that sound okay?

A. Yeah, that's fine.

MS. LEONARD: I can also try to send another copy again in the meantime. I'm not sure what's going on. But might as well give it a shot.

MR. SUTHERLAND: Sure.

BY MS. NELSON-MAJOR:

Q. So we were talking about the article by Wang, et al., that you cite for the proposition that, "Midazolam has been demonstrated to effect experiences of pain in a dose-dependent fashion."

In the Wang article the authors discuss a number of studies on the impact that midazolam had on different aspects of brain functioning; is that

right?

A. In the general context, that's correct.

Q. And one study the authors looked at specifically was about the impact midazolam has on brain activity related to pain. Is that the study on which you're basing your opinion that, "Midazolam has been demonstrated to effect experiences of pain in a dose-dependent fashion"?

MR. SUTHERLAND: Yeah, Ms. Nelson-Major, I would -- I'm going to request that he -- if you're going to refer to specific areas, I'd like you to be able to show it to him, so he can review it, so we're not talking in generalities. I think those are specific questions. I still haven't received it yet.

MS. NELSON-MAJOR: Mr. Sutherland, this is an article you provided to us. I don't know if you have access on your own system to those documents, but that's another option if it continues to not go through to you.

MS. LEONARD: Or should I -- could I send it to Rob Mitchell or Dean? Or is there someone else I could maybe try to send it to you? I'm open to suggestions.

MR. SUTHERLAND: Yeah, you can try to

send it to Rob and Dean. I don't know why it would make a difference, but you're certainly welcome to try.

MS. LEONARD: Okay, I'll try that now.

MR. SUTHERLAND: Yeah. I just got both of them at the same time. All right. And a third. On its way.

THE WITNESS: Okay.

BY MS. NELSON-MAJOR:

Q. Is this the Wang article that you cite in your report?

A. That's correct.

Q. I'm going to mark this as Exhibit 12 -- 13. Sorry about that. And we just agreed that this article surveyed a number of studies about the impact midazolam has on different parts of brain functioning, correct?

A. That's correct. That was the premise for them doing the study.

Q. And you specifically rely on this article for discussion of the impact that midazolam has on the human brain related to pain; is that correct?

A. That's correct.

Q. And, in particular, the Wang authors discuss a study on page five of this article. I'm

looking at the bottom of page five, and there's a citation in their discussion of the studies of midazolam and pain.

A. Which citation numbers are you talking about?

Q. I'm looking at citation 61.

A. Okay.

Q. Which is an article by Wise, et al. entitled: "The anxiolytic effects of midazolam during anticipation to pain revealed using fMRI."

Was this the study that you relied upon when you said, "Midazolam has been demonstrated to effect experiences of pain in a dose-dependent fashion"?

A. These research and review that was performed by Wang and their group is why I'm relying on that, in addition to that study. But the last sentence of that paragraph is actually where it talks about dose-dependent manner.

Q. And looking at that study referenced in that paragraph that I just mentioned by Wise, et al., did you read that particular study?

A. Did I pull the Wise study? No, I did not pull the Wise paper. I pulled and researched and found this research paper, which is why I referenced

it.

Q. And I understand that you didn't read the Wise study. But what does the word "anxiolytic" in the title of that study mean?

A. Anxiolytic from -- as just a general definition, means anxiety. But I don't know how they actually used it in that particular study, because there are varied definitions.

Q. What is anticipation to pain?

A. I guess I don't follow.

MR. SUTHERLAND: Object to the form.

THE WITNESS: Yeah.

BY MS. NELSON-MAJOR:

Q. Are you aware of the concept anticipation to pain?

A. I am aware of that, yes.

Q. And what does that concept refer to?

A. It's actually most often used in the setting of surgery, so in the -- again, the setting of care, treatment, diagnosis, and healing, where the patient is anticipating pain before a procedure or surgery.

Q. So it's distinct from the experience of pain itself.

A. It's part of the experience overall,

because you're anticipating what's coming toward you.

Q. Anticipation of the pain that might occur is different, though, than the actual experience of the pain that does in fact occur. Would you agree with that?

A. I have reviewed and understand it as an umbrella term, it is one of the same.

Q. Are you aware that the Wise study found that midazolam had no significant effect on brain activity associated with experience of pain, as opposed to the anticipation to pain?

MR. SUTHERLAND: Object to the form based on his prior answer.

THE WITNESS: No, because I have not reviewed the Wise study, so I can't comment.

BY MS. NELSON-MAJOR:

Q. When you say that, "Midazolam has been demonstrated to effect experiences of pain," is that the same thing as saying that midazolam has an analgesic effect?

MR. SUTHERLAND: Object to the form.

THE WITNESS: If analgesia, and part of it is experiencing and anticipation of pain then, yes.

BY MS. NELSON-MAJOR:

Q. And what does analgesia mean?

A. Analgesia, from my understanding and background and experience, is the treatment of pain.

Q. So, in your opinion, midazolam has an analgesic effect?

A. No, that's not what I said at all.

Q. So explain to me why that's an incorrect statement.

A. Why midazolam has an analgesic effect?

Q. Well, you said, "That's not what I said at all." Then can you explain to me what you did say? Because I think I misheard you.

A. Correct. Based on the dosage, the route of administration of two doses of 250 milligrams of intravenous midazolam, the person will be rendered unconscious, insensate, so will not experience any pain. I never said midazolam was an analgesic.

Q. At a clinical dose does midazolam affect the experience of pain?

A. How would you define clinical dose?

Q. I would defer to your definition of what a clinical dose is.

MR. SUTHERLAND: Object to the form.

THE WITNESS: Between one and five

milligrams? No. IV.

BY MS. NELSON-MAJOR:

Q. And at what dose does midazolam start to have an effect on the experience of pain, in your opinion?

A. At doses administered for anesthesia induction and/or in the setting of rapid sequence intubation, which is used therapeutically pretty commonly.

Q. So just to be clear, in your opinion, midazolam does not have an analgesic effect, but it does experience -- does affect experiences of pain; is that right?

A. That's correct, likely related to it rendering the person unconscious and unaware and unresponsive to physical stimuli, or insensate.

Q. So in your report you list three clinical uses of midazolam --

A. One sec. Sorry, let me just pull up the report.

Q. Page seven.

A. And you said page seven?

Q. Uh-huh. Yes. And then subheading number four.

A. Sure.

Q. You list three clinical uses in this section, you say that it's used as a procedural anesthetic, as an induction agent in anesthesia, and third, in the Intensive Care Unit while patients are on a mechanical ventilator or life support.

Are those the three uses of midazolam that you're aware of?

A. No. That's why the sentence doesn't say, "only."

Q. What other uses of midazolam are you aware of?

A. Many. It could be used for patients not on the mechanical ventilator that need comfort when having difficulty breathing, it can be used for acute agitation, that's not listed on there, it could be used for refractory status, that's given as intramuscular, it can be given as an infusion for refractory status epilepticus, which is, again, repetitive seizures that aren't broken with normal therapies. Those would be probably the predominant ones.

Q. And what's refractory status?

A. Seizures that are continuing to occur despite therapy or treatment.

Q. Then you write in the next sentence, "In

regards to the procedures, low dose midazolam is commonly utilized for procedures such as cardiac catheterization and endoscopy."

What do you mean by the term "low dose"?

A. From my understanding and background, training, experience is, that would be anywhere from 0.5 milligrams to 5 milligrams either given, and generally given, in sequential amounts. So the total could be 5, but it may not be, and generally is not, five milligrams all at with once for adult patients.

Q. Is midazolam used by itself during cardiac catheterization procedures?

A. From what I've observed, yes, it can be.

Q. Is it often accompanied by an opioid?

A. It depends if the patient's saying they're having pain. But oftentimes it's not. Which is the catheter going through their femoral artery and then with a camera viewing, after shooting the dye, the structural relative patency of their coronary arteries.

Q. And you said an opioid can be given if a patient says they're in pain. Does that mean that the patient is awake during the procedure?

A. That's correct. That's why it's called

conscious sedation, not unconscious sedation.

Q. So midazolam is used to achieve conscious sedation during a cardiac catheterization?

A. That's my understanding of why it's used, that's correct. And as an anxiolytic.

Q. Is midazolam used by itself during endoscopy?

A. It can be, that's correct.

Q. Is it sometimes given with other drugs?

A. Depends. If they're actually doing a colonoscopy and an endoscopy, which is maybe not as preferred for the patient then, yeah, they might mix it with an opioid, because they're going to be there for a little bit longer period of time.

Q. And why in that circumstance would an opioid be added?

A. I guess in layman terms, they're sticking a scope up their bottom and they're putting a scope down their throat and they're going to be there for a couple hours. So generally they will provide a small amount of an analgesic for comfort while the patient's awake the entire time.

Q. Then you write, "However, when an increased level of the depth of sedation and level of consciousness are needed then escalating doses

are required."

Are you referring to needing an increased level of sedation during an endoscopy or a cardiac catheterization here?

A. No. That's why it's separated, because it says when you need an increased level of depth of sedation. And what we just discussed -- oh, sorry, I wasn't done.

Q. I'm sorry. No, please finish your answer. I thought you were done.

A. The scenarios described above are conscious sedation. The ones described below, in my opinion, are considered more depth of sedation, which is not conscious sedation, it's deep.

Q. When you say the procedures discussed below, are you referring to rapid sequence intubation?

A. That would be a moderate to deep sedation, in my opinion, type of procedure, yes. Or deep sedation for a patient on the mechanical ventilator, if that's what's required.

Q. When a patient is placed under deep sedation for a mechanical ventilator, is midazolam given by itself in that context?

A. Depending on -- oh, sorry, go ahead.

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: The answer is, it depends, it depends on your scenario and it depends on the patient. Oftentimes it's combined with an opioid to achieve deep sedation in the context of the mechanical ventilator, a depressed RASS score, in the context of treatment and healing.

BY MS. NELSON-MAJOR:

Q. And why in the context of a mechanical ventilator is an opioid often given?

A. The opioid is pared because it acts on the mu receptor, which is the pain receptor.

Q. Does midazolam act on that receptor?

A. Midazolam does not act on the opioid receptor, no, nor do barbiturates.

Q. And you refer to that receptor as the pain receptor?

A. Mu receptors, mu 1 and 2, or m and u, are considered the pain receptors. There's a mu 3, but I don't think it's as clearly defined.

MR. SUTHERLAND: Ms. Nelson-Major, we've been going about an hour and a half. Do you mind if we take about a -- I don't know,

maybe a ten-minute break, restroom break?

MS. NELSON-MAJOR: That's fine.

VIDEOGRAPHER: Going off the record, the time is 1:01.

(A brief recess was taken.)

VIDEOGRAPHER: Back on the record, the time is 1:10.

BY MS. NELSON-MAJOR:

Q. Dr. Patel, I want to ask you a couple of questions about rapid sequence induction. First the basic one, what is rapid sequence induction?

A. Rapid sequence induction is, from my understanding and experience has been, more related to what I understand as RSI, which is rapid sequence intubation, where a patient needs a tube in the airway. And that plastic tube is placed by a trained professional, generally an anesthesiologist or a resident or a CRNA, or even EMTs.

Prior to that placement of that tube and procedure, the first drug actually is midazolam, and it could be in a range from anywhere from 0.4 up towards 0.6 milligram per kilogram if even used prior to surgery.

Q. And I meant to say intubation. So thank you for correcting me.

A. No problem.
Q. And it's often referred to as RSI for short; is that right?
A. That's correct.
Q. And under what circumstances is RSI performed?
A. The circumstance, it's generally -- the two I'm aware of, it's either emergent, so the patient's having very difficult time breathing, either ventilating or oxygenating; so either the mechanics of moving the air in and out or exchanging oxygen and carbon dioxide. So that can be either very quick or urgent, where it's seconds to minutes are needed. Or, it could be a controlled setting where they have the tube placed and the support during a surgery, whether it's elective or not.
Q. And in the emergent context you mentioned, the patient is usual unstable; is that right?
A. That's correct. That clinical context, the patient could be unstable, they could have abnormal blood pressure or heart rate or both. And there could be a number of other things going on. But it depends on the scenario.
Q. Potentially, that patient is non-fasted?
A. Non-fasted meaning they haven't been fa--

is what you mean they've eaten in the morning or that day?

Q. In general, before a non-emergent surgical procedure patients are instructed to fast; is that correct?

A. Well, that's actually changed over the years. So more recently, from what I'm familiar with, some of the surgeries just require no food two to four hours before, some even require liquids that are acceptable two to four hours before. So that's actually changed from what it was 10 or 20 years ago, from my understanding.

Q. And why is it rapid, in a rapid sequence induction?

A. My understanding is, because the effect of the drug is within seconds. So, generally, it's like a 30-to-60-second time window before the placement of the plastic tube in their throat.

Q. And when a patient is being intubated for a non-emergency surgery, is intubation done differently than an RSI procedure?

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: I'm not aware or have an opinion that they're different. My

observation is, the medicines and what's being used is virtually the same.

BY MS. NELSON-MAJOR:

Q. In your report you say that midazolam is used as a "sole agent" during RSI. What do you mean by "sole agent"?

A. Sure. Let me just get to it. Which page were you referencing?

Q. I'm looking for the exact --

A. Just so I can get the context correct.

Q. The bottom of page seven onto the top of page eight, the sentence carries over.

A. That is correct, it is the first drug administered.

Q. And what other drugs are administered?

A. After the benzodiazepine, it's a paralytic, like vecuronium or succinylcholine or rocuronium.

Q. Is a pre-treatment drug often given prior to beginning RSI?

A. It depends on the setting and availability of the medicine.

Q. If a pre-treatment drug is available, is it generally given before beginning RSI?

A. That's correct, it can be given prior.

Q. My question is, if it is available, is it usually given?

A. Correct, if the providers have access to it and can administer it in a timely fashion, they would.

Q. And what type of drugs are used as pre-treatment?

A. It would be a low dose of fentanyl, it could be a low dose of ketamine. Those would be two examples.

Q. And what kind of drug is fentanyl?

A. Fentanyl is an opioid.

Q. And what about ketamine?

A. It's a phencyclidine, classified under the anesthetics.

Q. And why are those types of pre-treatment drugs given when they're available?

A. They augment the activity of the benzodiazepine.

Q. And after the endotracheal tube is placed, are other drugs given?

A. I guess I don't quite understand. Other drugs for -- for what?

Q. Let me clarify. Are analgesics or additional sedation drugs generally given after an

endotracheal tube is placed during an RSI procedure?

A. After the placement, that's correct.

Q. And what sorts of additional sedation drugs or analgesics are generally given after placement of an RSI tube?

A. Sure. About 30 to 45 minutes after the procedure you'll have initial wearing off of the induction agent, and in that instance an opioid is usually administered, in that scenario and in that context.

Q. And then on to page eight. I'm looking for the exact sentence to point you to. The last sentence in that paragraph you write, "The role of midazolam administration for this procedure is to provide relaxation of the airway muscles while inducing an amnestic effect." Do you see that sentence?

A. That's correct.

Q. What does amnestic mean?

A. From my understanding and from what I have learned over the years, it creates a state of amnesia.

Q. And what is a state of amnesia?

A. Not being able to remember the procedure or recall it.

Q. So amnesia is different than analgesia; is that correct?

A. That's correct. That's why it doesn't say analgesic.

Q. So the role of midazolam in an RSI procedure is to relax the airway muscles and induce an amnestic effect. Am I paraphrasing that correctly?

A. That's correct, before the placement of the plastic tube in their throat, which is painful, causes coughing and gagging, they're administered a drug for anxiolysis and an amnestic effect. That's a hundred percent correct.

Q. And anxiolysis means reduction in anxiety, correct?

A. That is correct. That's one of the purposes, besides sedation.

Q. So the midazolam given in an RSI procedure isn't intended to induce an analgesic effect, correct?

A. That's correct.

MR. SUTHERLAND: Object to form.

THE WITNESS: I'm sorry, go ahead.

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: It's intended, as I stated, before the placement of the plastic tube and the coughing and gagging, to produce a state of unconsciousness, relaxation, and sedation.

BY MS. NELSON-MAJOR:

Q. In your clinical practice at the University of Chicago Medicine, do you typically see ketamine, etomidate, or midazolam being used as the first drug in an RSI procedure?

A. Well, I don't administer the drugs, so I don't have an opinion. My experience from dispensing the medicines is, it could be any one of the three.

Q. I'm going to pull up the product labeling for midazolam that you cite in your report. And I'll give you a minute for that to arrive to Mr. Sutherland.

MS. LEONARD: Sorry, the delay was my fault this time. I just sent it to you.

MR. SUTHERLAND: No, that's all right.

MS. LEONARD: Just making sure I had the right thing.

MR. SUTHERLAND: That's okay. Here it is. I just sent it to you, Dr. Patel.

THE WITNESS: Yep. Got it.

BY MS. NELSON-MAJOR:

Q. Is this the midazolam product labeling that you cite in your report?

A. That's correct, this is the one approved and reviewed by the Food and Drug Administration for manufacturers, in this case it's Akorn.

Q. I'm going to mark this as Exhibit 14. Could you please turn to page 17.

A. Sure.

Q. So at the bottom of the page you'll see it says, "USUAL ADULT DOSE" in bold and capital letters?

MR. SUTHERLAND: I'm going to be dense here, but I'm not seeing pages.

THE WITNESS: Yeah, I'm not seeing that either.

MS. NELSON-MAJOR: I'm wondering if we are looking at different product labeling.

MR. SUTHERLAND: This says, "Midazolam, Akorn, Inc." But it doesn't have page numbers on it.

MS. NELSON-MAJOR: Oh, I'm looking at the pdf page numbers, if that -- no?

MR. SUTHERLAND: Oh, they're just --

oh, I see what you're saying.

MS. NELSON-MAJOR: They're not marked on the page, the numbers.

MR. SUTHERLAND: Got you.

THE WITNESS: And it's page 17?

MS. NELSON-MAJOR: Correct. At the very, very bottom it should say, "USUAL ADULT DOSE."

THE WITNESS: I see that. Yes. Sorry, I was looking for the page number.

BY MS. NELSON-MAJOR:

Q. It's a little bit confusing. My apologies.

Does this portion of the product labeling lay out the approved uses of midazolam?

A. The approved uses? No, I believe these are the approved or at least recommended as reviewed by the Food and Drug Administration, again, in the setting of care, treatment, diagnosis, and healing. That's correct.

Q. And the first portion is about intramuscular administration. Do you see that?

A. I see that, yes.

Q. I'm scrolling down to the next page, 18, where intravenous uses are discussed. Let me know

when you see that.

A. I see that, yes.

Q. And under the word "INTRAVENOUSLY," do you see that it says, "Sedation/anxiolysis/amnesia for procedures"?

A. Procedures -- that's correct. Procedural sedation.

Q. And that's what we've been talking about in the context of RSI and cardiac catheterization?

A. This is in the context of, from what I saw there, bronchoscopy, which is where they shove a scope down the throat to look at the lungs. At least that's what I'm reading.

Q. Okay. Well -- and is endoscopy a kind of bronchoscopy procedure?

A. No, bronchoscopy is specific to putting a camera down the throat and looking at the lungs. Endoscopy, from my understanding, is putting a camera down the esophagus to look at the esophagus and stomach.

Q. A bronchoscopy is a different procedure, in your opinion.

A. Bronchoscopy is specific for broncho, which is lung. Endoscopy, or endo, is for the GI system. They're two different organ systems.

Q. Did you see that it says for bronchoscopy procedures, the use of a narcotic premedication is recommended?

A. That's correct.

Q. Why is the use of a narcotic premedication recommended?

A. It says right there, because they're using a reduction in dosage of midazolam. Reduction is less, not more.

Q. Are you referring to the first sentence after the colon in this paragraph that reads, "Narcotic premedication results in less variability in patient response and a reduction in dosage of midazolam"?

A. That's correct, less drug.

Q. And what --

MR. SUTHERLAND: I'm sorry, Ms. -- I'm sorry, where are we?

MS. NELSON-MAJOR: We're in the paragraph that's titled: INTRAVENOUSLY.

MR. SUTHERLAND: Right.

MS. NELSON-MAJOR: And under that there's a sentence that states, "Sedation/anxiolysis/" --

MR. SUTHERLAND: Got you.

MS. NELSON-MAJOR: -- "amnesia for procedures."

MR. SUTHERLAND: Yeah.

MS. NELSON-MAJOR: And I'm directing Dr. Patel to the sentence that reads, "Narcotic premedication results in less variability in patient response and a reduction in dosage of midazolam."

MR. SUTHERLAND: Got it.

BY MS. NELSON-MAJOR:

Q. What does patient response mean in this context?

A. Well, patient response means just how the patient responds and what clinical effect it will have on them in regards to the therapeutic dose range administered.

Q. And then the next sentence says, "For peroral procedures, the use of an appropriate topical anesthetic is recommended."

Why is a topical anesthetic recommended when midazolam is used for a peroral procedure?

A. For the placement of the ET tube, as time allows, they would use topical lidocaine.

Q. And why if time allows would you use topical lidocaine?

A. It actually goes to the procedure itself, so -- I'm not sure if you're familiar. But from my observation, the topical lidocaine isn't something you dump in the throat; they have to actually draw it up in a syringe, and then you use what's called an atomizer, attach it to the end of the syringe, and then it's sprayed.

It allows the plastic tube to glide into the throat, to minimize as much as possible the coughing, gagging, and offer a little bit of -- very little, if any, pain support while they're doing a procedure.

Q. And how does the lidocaine ensure that the tube -- I think you said to guide the tube down the throat? Is that what you meant?

A. No, the topical lidocaine is administered before the tube is placed. To guide the tube placement is via a laryngoscope, with a handle. So the blade actually has a light at the end of it. And that opens up the patient's -- from my understanding and observation, their throat and then they place the tube.

The topical lidocaine is sprayed and administered before they do that. But it doesn't come that way, it comes as a liquid. So from what

I've observed, you have to actually draw it up in a syringe, put an atomizer, which is a particle reducer, at the end of the syringe, if you have one, to actually get the drug to where you want it to go, at the right dose, at the right time, all before -- within seconds of placing the tube.

That's why I said, it's not always done, nor do you have time for it.

Q. But when you have time for it, you administer the lidocaine to reduce the patient's response to the pain and noxious stimulus of the tube being inserted?

A. That's correct, that can be done in a therapeutic and controlled setting.

Q. And so moving on to the second use of midazolam that you identified in your report, as an "induction agent." What do you mean by "induction agent"?

A. It's given prior to the start of anesthesia.

Q. And induction of anesthesia is different than maintenance of anesthesia, correct?

A. I would defer to an anesthesiologist. I don't have an opinion on that.

Q. But do you have an opinion on the use of

midazolam as an induction agent in anesthesia?

A. No. Negative. I just said it's used as an induction agent because it is.

Q. But you don't know whether it's used or not to maintain general anesthesia?

A. I'm not an anesthesiologist. I don't administer the drug. So I defer to an anesthesiologist.

Q. I'm just trying to understand how you're able to offer an opinion on the appropriate use of midazolam as an induction agent but not whether or not it's an appropriate agent to be used for maintenance of anesthesia. Can you help me understand why one falls within your expertise and one doesn't?

A. They're both referenced. My experience and what I've viewed and my practice over the 20 years is that it's commonly used as an induction agent. That's why that's my opinion. And it's actually cited as an approved use. It's not anything new.

Q. And you have no opinion on whether midazolam is capable of maintaining general anesthesia at any dose?

MR. SUTHERLAND: Objection to form.

THE WITNESS: Maintenance of general anesthesia? No, I defer to an anesthesiologist.

BY MS. NELSON-MAJOR:

Q. Earlier you referred to deep sedation, as opposed to conscious sedation; is that right? They're two distinct categories?

MR. SUTHERLAND: Object to the form.

THE WITNESS: Conscious sedation would be having the patient almost fully awake and responsive during the procedure. And, correct, when they're on the mechanical ventilator, sometimes that calls for a deeper level of sedation, that's true.

BY MS. NELSON-MAJOR:

Q. I want to ask you a couple of questions about vecuronium bromide. What class of drugs does vecuronium bromide fall within?

A. It would be neuromuscular blockers.

Q. And on page nine of your report, under "Pharmacologic properties" -- do you see that subheading?

A. I do, yes.

Q. You wrote, "After administration the vecuronium will take effect within two [to] three

minutes."

What do you mean by "take effect" in this sentence?

A. In a therapeutic setting, at that dose, it would have neuromuscular blocking properties within a two-minute timeframe.

Q. So you're not talking about peak effect, are you, when you say it'll take effect within two to three minutes?

A. This would be -- because it is a fairly rapid-acting drug, comparative to the sedatives, it peaks, and would easily, within two minutes, you'd have full neuromuscular blockade. The peak's going to be a lot -- the onset is faster than the peak; if it wasn't, you wouldn't be waiting two or three minutes to perform an intubation.

Q. Does the two-to-three-minute window change with different doses?

A. I don't believe it'll change all that much with a different dose, for this particular drug.

Q. So, in your opinion, onset times are not progressively shorter with higher doses of vecuronium?

A. There are a couple of papers that have referenced a faster onset time as the dose is

escalated, that's correct, that's been published.

Q. And do you agree with those studies?

A. That it's faster the higher the dose administered? That's correct. The same is said for midazolam.

Q. And what do you base your opinion that the vecuronium bromide will take effect within two to three minutes after administration?

A. It's not my opinion, that's what's cited in the product labeling and in the references, for that dose, for that scenario.

Q. Are all --

A. Sorry, go ahead.

Q. No, my apologies, I thought you were done. Please finish.

A. No, it's -- the reason I point that out, and make a point to do this for a second, is that it's clear -- for example, if you go back to the midazolam pack product labeling, it has effect of -- there's places in the product labeling where it says one to two minutes, two to three minutes, 30 to 60 seconds. So it is dose dependent. But that's why I mention that.

Q. Are all muscle groups impacted at the same time following administration of vecuronium bromide?

A. It acts on the neurotransmitter acetylcholine and blocking it. So my opinion is, yes, that will take place all relatively at the same time.

Q. Have you ever dispensed vecuronium bromide for use on a patient?

A. In the clinical context for patient care, I have, yes.

Q. For what purposes?

A. Neuromuscular blockade.

Q. And at what doses?

A. You don't dis-- I'm sorry, the question doesn't make sense. You don't dispense a dose, you dispense the vial or the syringe.

Q. So you don't fill a prescription for a certain dosage?

A. No. I apologize, the question doesn't make sense. You dispense the syringe or the premanufactured vial.

Q. When a prescription is written and you receive that prescription, does it tell you what the dose to be administered will be?

A. Negative, because the provider will dictate the dose and how many doses they'll need to give, whether it's one timed dose or in increments,

depending on the situation.

Q. How do you know how many vials to provide then?

A. I'm sorry, the question doesn't make sense. The vials are already there at the provider's hands. They're diluting and administering it on site depending on how much they need. Are you asking for what a normal dose is?

Q. I'm asking for what the clinical range of doses are that you've given of vecuronium bromide in your clinical experience.

A. I have never given vecuronium bromide to a patient. I've dispensed it for a patient. Is that what you're asking, for the therapeutic dosage range? I'm sorry, I don't understand.

Q. My question is, the vecuronium bromide that you've dispensed to a patient in a clinical setting, what is the clinical range of doses of vecuronium bromide?

A. The clinical range would be 0.04 milligram if it's just a bolus up to 0.1 milligram per kilogram, depending on the scenario, and if they're re-dosing and it it's a one-time dose. At least that's been my understanding and experience. Which would be encompassed in less than one 10-milligram

vial.

Q. Have you ever seen vecuronium bromide administered to a patient without an anesthetic or analgesic?

A. Have I seen vecuronium --

MR. SUTHERLAND: Object to the form.

THE WITNESS: Oh, sorry, go ahead.

MR. SUTHERLAND: Object to the form. You can answer.

THE WITNESS: Sorry, could you repeat the question?

BY MS. NELSON-MAJOR:

Q. Have you been present when a medical professional has administered vecuronium bromide to a patient without first giving them a premedication of an anesthetic or an analgesic?

A. No. I don't have an opinion. I don't think I've ever been present when that's happened.

Q. Does administration of the vecuronium bromide without an anesthetic agent cause pain?

MR. SUTHERLAND: Object to the form.

THE WITNESS: I don't have an opinion. I can't answer that. I've never been present when they've administered.

BY MS. NELSON-MAJOR:

Q. What I'm asking is, does the administration of vecuronium bromide cause pain on a patient? I'm not asking whether you've been present.

A. Oh, I'm sorry, I didn't understa-- because your first question was, when you were present and they didn't give the pre-anesthetic, does it cause pain. So that's why I was confused. So you want to know if it's given -- I don't understand your question.

Q. My first question was, and you've answered it, was have you ever seen vecuronium bromide administered without an anesthetic or analgesic premedication, and you said no.

My new question is, does administration of vecuronium bromide without a premedication of an analgesic or anesthetic cause pain to a patient?

A. Does a therapeutic dose of vecuronium cause pain to a patient --

Q. Yes.

A. -- within out the pre-anesthetic?

Q. Yes.

A. I'm not sure it would cause pain. It depends on what they're doing if they didn't give

the pre-anesthetic. It would leave them paralyzed.

Q. And if a patient was not given an analgesic or a sedative drug before that vecuronium bromide was given, what would that feel like to a patient?

A. They would be aware of their surroundings and the surgery.

Q. And would they be aware of their paralysis?

A. I'm not sure they'd be aware of the paral-- they'd just be paralyzed. So, yeah, I guess they would be aware that they can't move their extremities.

Q. And if they were given a sufficient enough dose that their breathing muscles were affected, would they experience air hunger?

A. It would be air hunger and/or death if the airway isn't supported, which unfortunately has occurred in medication errors, one recently, actually.

Q. And on page nine of your report you write, "As vecuronium does not affect the level of consciousness it is recommended to administer an anesthetic sedative prior to vecuronium."

Why is it recommended that an anesthetic

sedative be administered prior to vecuronium?

A. It's to depress the level of consciousness and awareness.

Q. And why would you want to depress the level of consciousness or awareness before administering vecuronium bromide?

A. In the rapid sequence intubation, it's so that they're not aware that they're paralyzed, so that the provider or clinician can carefully put in placement for the airway support, or the plastic tube.

Q. And why in a clinical setting would you want to prevent a patient from being aware of the fact that they're being paralyzed?

A. It's been described that they would feel trauma, when they were questioned after being awakened.

Q. And trauma from what?

A. I believe they referred to it as post-traumatic stress disorder. So they could have nightmares or visions or dreams.

Q. And you wrote that it's recommended that a premedication anesthetic be given before the vecuronium. Where does that recommendation come from?

A. I believe it's from the product labeling. But any of the clinical guidelines in critical care or anesthesia likely discuss the same principle, in a therapeutic context.

Q. Once the vecuronium bromide has taken effect, will an inmate be able to move or signal if they're experiencing pain during execution?

A. I don't believe at this dose, at the 500-milligram dose of midazolam, again, given in 250-milligram increments intravenously, and after vecuronium bromide is administered, will the inmate be able to signal, no.

Q. And that's because they're paralyzed?

A. That's because of the first drug administered in the protocol.

Q. What I'm asking is, if a patient does in fact experience pain -- and I'm asking you to assume that in this hypothetical -- will they be able to signal pain following administration of the vecuronium bromide?

A. That's dependent on the midazolam dose.

Q. And if, say, a vein was to rupture and the midazolam didn't make it into the vascular circulation and the person did not receive the full dose of midazolam, or even any midazolam, following

the vecuronium bromide would that person be able to signal if they were experiencing pain?

A. Well, that would be difficult to hypo-- in a hypothetical, because you would see that amount of 50 to 100 cc's of fluid sitting in their arm, so you wouldn't administer the vecuronium.

Q. What class of drugs does potassium chloride fall within?

A. Potassium chloride is considered an electrolyte.

Q. And have you dispensed potassium chloride for a medical professional to administer to a patient?

A. I have, yes.

Q. And for what purposes?

A. It's to therapeutically replace a potassium loss either in the context of diuresis or fluid loss or potassium wasting that occurs from GI loss or diarrhea, or in the context of cardioplegia where they in fact get a potassium vial.

Q. And what's cardioplegia?

A. Cardioplegia is the fluid a perfusionist uses during bypass surgery.

Q. And during bypass surgery, is potassium

chloride used to stop the heart from beating?

A. That's correct, that's its intended purpose after the aorta is clamped off, the cardioplegia is infused.

Q. And in a clinical setting, what is the maximum concentration at which potassium chloride is given?

A. It depends on which clinical setting.

Q. Out of those clinical scenarios you just outlined, which of those clinical scenarios uses the highest concentration of potassium chloride?

A. It's actually the one where you're just replacing it from potassium lost, because the cardioplegia one could be 40 mil equivalents or more in a liter, the others are 20 to 40 mil equivalents in 100 mLs of fluid.

Q. Is an injection of a clinical dose and clinical concentration of potassium chloride painful if the patient isn't adequately sedated?

A. From my background, training and experience and from seeing nurses give it at the bedside, patients experience a sting, most reflect on it as a mosquito bite.

Q. What about a bolus dose of 250 mil equivalents as called for by the protocol, what

would that feel like?

MR. SUTHERLAND: Object to the form.

THE WITNESS: I don't know what it'd feel like. I don't know if that's ever been studied nor ethically done in a patient care context.

BY MS. NELSON-MAJOR:

Q. I'm going to pull up the potassium chloride labeling that you cited in your report. And Ms. Leonard will e-mail that to Mr. Sutherland.

MR. SUTHERLAND: Got it, and on its way.

A. Okay, this one was vecuronium. Is that what you're -- is that the one you're talking about?

Q. I might have misspoke. I meant to pull up the potassium chloride product labeling.

MS. LEONARD: One second. I'll send that right now.

MR. SUTHERLAND: Dr. Patel, are you thinking you're going to be good on the meeting?

THE WITNESS: Yeah, I was just checking. That's fine.

MR. SUTHERLAND: I just got it, and it's on its way.

THE WITNESS: I got it. Okay.

BY MS. NELSON-MAJOR:

Q. Is this the potassium chloride product labeling you cite in your report?

A. That is the one referenced, that's correct.

Q. I'm going to mark this as Exhibit 15, and ask you to turn to page five. Take a look at the first highlighted sentence.

A. Okay.

Q. So it states that, "Administration via a central route is recommended for dilution by the blood stream and avoidance of extravasation, as well as to avoid the pain and phlebitis associated with peripheral infusion."

What does extravasation mean?

A. That's what we talked about earlier when, I believe -- and I respectfully disagree with Dr. Almgren and Dr. Stevens when they were commenting on the pH of midazolam being extremely or excruciatingly painful, which has nothing to do with it. It actually has to do with extravasation. And extravasation is when the drug gets outside of a vessel.

Q. And what does phlebitis mean?

A. Phlebitis is kind of an umbrella term for inflammation of the vessel.

Q. When potassium chloride is administered at your work, is it generally administered via a central route?

A. It's patient dependent. I would say the majority is actually administered, more than 50 percent, peripheral. It's because there's actually a number of cautions and dangers associated with central lines, one of those being infection.

Q. And why does the product labeling recommend central route administration despite those concerns?

A. It has to do with the thickness of the vessel. So, many times the peripheral vessel in the hospital is the antecubital fossa, which I believe is the main vein in the inner elbow, which is what is used in the TDOC protocol, I believe.

Q. I'm not understanding the connection between the size of the peripheral vein and this warning in the potassium chloride monograph. Can you explain to me why the product labeling says that potassium chloride should be administered via the central route?

A. Sure. It has to do with the thickness of

the blood vessel, and it has to do with the amount of dilution that occurs with the drug after administered. In a therapeutic setting, as I mentioned, more than 60, 70 percent is peripheral, and it's because of the risks and the safety associated with central line placement.

Q. So do you disagree with this recommendation in the product labeling that potassium chloride should be administered via central route?

MR. SUTHERLAND: Object to the form.

THE WITNESS: No, I never said I disagree with it. I'm telling you what happens around hospitals all over the country.

BY MS. NELSON-MAJOR:

Q. Do you -- what is the connection between the size of the peripheral vein and why this product labeling makes the recommendation that the potassium chloride be administered by a central route?

A. In a therapeutic dose the idea and thought is, is that the pain and phlebitis is minimized with the central vein administration, it doesn't eliminate it.

Q. And you described the pain and phlebitis as a mosquito bite; is that correct?

A. That's correct. And that wasn't my description, that's what patients have said.

Q. Why would a product labeling recommend a central route to avoid the pain associated that's comparable to a mosquito bite?

MR. SUTHERLAND: Object to the form.

THE WITNESS: I don't know. You'd have to ask the FDA, who approved the verbiage for the product labeling, and Baxter.

BY MS. NELSON-MAJOR:

Q. And then the next sentence that's highlighted reads, "The highest concentrations of Potassium Chloride Injection (300 mEq [per] liter and higher) should be exclusively administered via central intravenous route."

What is 300 mil equivalents per liter in terms of mil equivalents per milliliter?

A. That would be -- oh, sorry, go ahead.

MR. SUTHERLAND: Object to the form.

THE WITNESS: In terms of milliliters, you would divide it by a thousand, so it'd be 0.3 mil equivalents per mL.

BY MS. NELSON-MAJOR:

Q. So according to the product labeling, if you're going to administer a potassium chloride

injection of higher than .3 mEq per mL, it should be done exclusively via central route; is that correct?

A. That's correct, as suggested by the -- and approved by the FDA in the context of treatment and healing.

Q. And what is the concentration of potassium chloride that TDOC uses during an execution?

A. The concentration, if I recall correctly, is 120 mil equivalents in 60 mL.

Q. Would that be 2 mEq per mL?

A. That's correct.

Q. And that's much higher than .3 mEq per mL?

A. That's correct.

Q. And why is the recommendation stated more strongly in the context of the high concentrations of potassium chloride in the product labeling?

MR. SUTHERLAND: Object to the form.

THE WITNESS: Sure. It's because this is reviewed in the context of efficacy and patient safety in the context of treatment and healing. And so that's what the FDA deemed appropriate for direct patient care.

BY MS. NELSON-MAJOR:

Q. And what I'm trying to understand is, what the pharmacological difference between a highest

concentration of potassium chloride and a standard concentration of potassium chloride that would lead the FDA to approve a recommendation that the high doses be exclusively administered via central line.

A. Well, my opinion, just my opinion, the recommendation doesn't actually make any sense. Because if we listen to what we're talking about, 300 mil equivalents in a liter in a therapeutic setting or in the setting of diagnosis, care and healing, per liter is only utilized in cardioplegia. Cardioplegia generally ranges from 40 to 80 mil equivalents in a liter.

In therapeutic setting and patients that are on the floor, if you're familiar, are generally in 20 and 40 mil equivalents in 100 mL. You would never approach 300 mil equivalents in a liter anyway.

Q. Well, my question is, why is the recommendation more strongly asserted for a higher concentration? Setting aside the actual number value associated with the higher concentration.

A. I couldn't -- I don't have an opinion. I don't -- I haven't reviewed what the FDA's reviewed. You'd have to ask them.

Q. So from a pharmacological standpoint, you

don't have an answer to why a higher concentration would warrant increased precautions in administration to a patient?

A. No, from a pharmacologic perspective, I'm telling you, therapeutically, I have never seen 300 mil equivalents in a liter. So that's why I have no opinion on it.

Q. I'm not asking about the value stated. I'm asking whether, as you increase the concentration of potassium chloride for administration to a patient, there's increased safety risks attendant with that increased concentration.

A. That's a different question. So, yes, there is. That's why they recommend central access.

Q. And what of those increased safety risks?

A. The safety risk is pain and phlebitis, as they stated above.

Q. And so that risk of pain and phlebitis increases as the concentration increases?

A. That's correct, in this therapeutic setting.

Q. Does the risk of pain and phlebitis with an increased dose not occur in a non-clinical setting?

MR. SUTHERLAND: Object to form.

THE WITNESS: Yeah, the question doesn't make sense, because you don't pre-medicate patients getting potassium chloride. So I don't understand the question.

MS. NELSON-MAJOR: My question -- court reporter, could you read back my last -- not this last question but the previous question, and the previous answer, please.

(The requested portion was read back by the reporter.)

THE WITNESS: That's my answer.

BY MS. NELSON-MAJOR:

Q. Well, let me clarify, because I'm not sure that my question was clear to you then. I asked whether the risk of pain and phlebitis increases with higher concentrations of potassium chloride. And your answer was, yes, in this clinical setting. And I'm trying to figure out the significance of the clinical setting piece of your answer.

A. The significance is, is exactly what we're talking about. If you're familiar with patients getting 20, 40 or 60 mil equivalents of potassium chloride, zero of them are pre-medicated; meaning, they are fully conscious and aware of anything,

that's why they describe the pain.

Q. And in those doses, what are the concentrations you're discussing? So I'm asking a question about concentration, not about dose right now.

A. Sure. It could be 40 mil equivalents in 100 mL or 20 mil equivalents in 100 mL. So that would be 0.2 mil equivalent for an mL.

Q. And that's lower than the concentration of potassium chloride that TDOC uses at an execution, correct?

A. Obviously, yes.

Q. Could you, please, scroll to page seven of the product labeling.

A. Okay.

Q. And do you see at the bottom portion of the page where it states, "General Disorders And Administration Site Conditions"?

A. That's correct.

Q. And it lists chest pain, infusion site pain, infusion site irritation, and burning sensation?

A. That's correct.

Q. And do you agree with those warnings?

MR. SUTHERLAND: Object to the form.

THE WITNESS: I'd agree that those are post-market adverse reactions, that's correct.

BY MS. NELSON-MAJOR:

Q. Let me go back to page one of your report.

A. Okay.

Q. I'm looking at the third paragraph in the Introduction section. The paragraph begins, "It is my opinion." Do you see that?

A. I do, yes.

Q. And then the second sentence reads, "Instead, based upon the chemicals used, the preparation, the dose and order of administration, the Protocol will result in the inmate being insensate during the transition to death."

What does "transition to death" mean here?

A. The act of dying.

Q. What point in the process as laid out by the protocol are you referring to when you use the term "transition to death"?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: Which part of the protocol -- I don't understand the question. The protocol is designed to cause death.

BY MS. NELSON-MAJOR:

Q. I'm very much aware of that fact. My

question is, when you say, "the Protocol will result in the inmate being insensate during the transition to death," I'm trying to understand at what temporal point in the execution process you're saying the inmate will become insensate.

A. It would be after the administration of midazolam.

Q. And then on page 14 -- if you could scroll to that page, please.

A. Okay.

Q. And I'm looking for the exact sentence. So at paragraph number two that begins, "My opinion is that following." Do you see that?

A. I do.

Q. So you wrote that, "My opinion is that following administration of the three chemicals as provided in the Protocol will result in the inmate being insensate."

Is it your opinion that the inmate will become insensate after the third drug is administered?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: That they will be insensate after the administration and completion of the first drug, which would be

midazolam.

BY MS. NELSON-MAJOR:

Q. And then you explain the basis for this opinion throughout this paragraph. And I want to ask you about the sentence where you write, "Midazolam injection demonstrates a dose-dependent effect (higher the dose [arrow] higher the effect) on the level of consciousness."

Is this dose-dependent effect limited by the ceiling effect we talked about earlier?

A. It would be limited by the ceiling effect if the ceiling effect is known, that's correct.

Q. And you earlier testified that in your experience and expertise, it was your belief that midazolam, like all benzodiazepines, have a ceiling effect?

A. The concept and the principle is applicable to benzodiazepine, that's correct. I'm not aware of any published literature that says what the dose is.

Q. And then building on this statement, you write that, "Midazolam has been demonstrated to effect experiences of pain in a dose-dependent fashion."

We already talked about the sentence a bit,

and you cited the Wang article in support. Are there other studies or articles that you're relying on for the proposition that midazolam has been demonstrated to effect experiences of pain, as opposed to the anticipation of pain?

MR. SUTHERLAND: Object to the form.

THE WITNESS: Not other than what we've already discussed, no.

BY MS. NELSON-MAJOR:

Q. And then moving down into page 15, you write that midazolam is an appropriate drug for lethal injection because it "disrupts the pathways of neuronal (electrical) activity between the key regions of the brain integrated to the perception and anticipation of pain." And, again, here you state --

MR. SUTHERLAND: I'm sorry, Ms. Nelson-Major, you say -- you started off saying, "midazolam is an appropriate drug for lethal injection." Where are you reading from?

MS. NELSON-MAJOR: I am reading from the top of page 15, the second full sentence, and it states, "Midazolam" --

MR. SUTHERLAND: Okay. "As midazolam is"?

MS. NELSON-MAJOR: No, the preceding one.

THE WITNESS: The one before it, yeah.

MR. SUTHERLAND: Okay. Okay.

MS. NELSON-MAJOR: Do you see where we are?

MR. SUTHERLAND: "Midazolam disrupts"?

BY MS. NELSON-MAJOR:

Q. "Midazolam disrupts the pathway of neuronal (electrical) activity between the key regions of the brain integrated to the perception and anticipation of pain; therefore, it is an appropriate drug for lethal injection." Do you see where we are, Dr. Patel?

A. Yes.

Q. And again you cite the Wang article for this proposition. Besides the Wang article, are there other studies or articles that support this proposition that you're relying on?

A. Outside of that, no. Because we don't have a paper evaluating in a therapeutic context 500 milligrams of midazolam.

Q. That's not what my question was. The statement that you've made here is that, "Midazolam disrupts the pathways of neuronal activity between

the key regions of the brain integrated to the perception and anticipation of pain."

My question is, besides Wang, do you have other articles or studies that you're supporting -- excuse me, that you're citing to support this proposition?

A. Other than anything referring to midazolam in my references, no.

Q. Then you state, "As midazolam is an acceptable first drug for RSI to facilitate a depressed level of consciousness, more likely than not it is acceptable to administer prior to vecuronium."

In your clinical practice, would you recommend the use of a drug on the basis that you thought it was more likely than not acceptable?

A. Absolutely. It's still used today and it's used by anesthesiologists all over the country, from what I've read and what I'm aware of.

Q. How confident are you in this opinion that because midazolam's an acceptable first drug for RSI, it's acceptable to administer prior to vecuronium in this case?

A. How confident am I? Well, if we take a step back and look at the therapeutic use of

midazolam, if it was not appropriate, which is what you're obviously insinuating and proposing, it would be ripped out of every textbook and every anesthesiology reference and every hospital for this indication, and it's not. So it is appropriate more likely than not.

Q. Dr. Patel, I'm not trying to insinuate anything. I'm just trying to understand your inclusion of the phrase "more likely or not," because that's not a phrase you used when expressing other opinions. So I'm just trying to understand whether you hold this opinion with a less degree of confidence than you hold the other opinions throughout your report.

A. No, there's no less degree of confidence than any of the other opinions.

Q. And are you saying that rapid sequence induction involves the same level of sedation necessary to render an inmate insensate to the pain and suffering of the second and third drug in the protocol?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: Based on the dosage and route of administration and the procedure, that's correct.

BY MS. NELSON-MAJOR:

Q. Do the studies you have in your opinion involve the same level of stimulus or pain?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: Repeat the question again?

BY MS. NELSON-MAJOR:

Q. You're drawing a comparison between RSI and TDOC's protocol for executing an inmate. And I'm asking you whether you're also drawing a comparison between the level of pain and suffering that might be experienced in an RSI and that might be experienced in an execution context.

MR. SUTHERLAND: Same objection.

THE WITNESS: The association and reason that statement's in there is because there is a lot of questions about, obviously, midazolam being the first drug in the protocol, is that in a clinical context even it's appropriate. So if it's appropriate in the clinical context, in the setting, in depressed level of consciousness and awareness, my opinion is that 500 milligrams is more than appropriate and adequate in the context that we're discussing.

I apologize if that's not what you asked, but that's what I was understanding you were asking.

BY MS. NELSON-MAJOR:

Q. So are you offering an opinion that the level of sedation required for an RSI is the same level of sedation required for the protocol to render an inmate insensate to the second and third drug?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: Well, now you're mixing -- it's apples and oran-- you're mixing -- it's not the same thing. One is a therapeutic context. And, again, the reason it's in there is that it's clear that even at a therapeutic dose at a significantly lower amount, it's appropriate to administer before a neuromuscular blocker.

So, yes, it is appropriate to administer in this setting at this dose for the intended consequence. That's my opinion.

BY MS. NELSON-MAJOR:

Q. And for support for the comparison you cite an article titled: "Neuromuscular blockade in the critically ill," by Renew, et al. I'm going to

ask Ms. Leonard to send that article to Mr. Sutherland. And while we're waiting for that e-mail to arrive to Mr. Sutherland, I just have one more question.

In the rapid sequence intubation context, patients aren't administered potassium chloride after the vecuronium bromide; is that correct?

A. Your question is, are patients administered potassium chloride after rapid sequence intubation?

Q. Yes.

A. I'm sorry, that doesn't make any sense, because that's an electrolyte replacement and your main focus is on the airway. So, no, they're not administered potassium chloride after. The main focus is to stabilize the airway.

Q. And we discussed the sensation that a patient might experience upon administration of the potassium chloride as being painful; is that correct?

MR. SUTHERLAND: Object to the form.

THE WITNESS: That's correct, that has been described.

BY MS. NELSON-MAJOR:

Q. And with increasing levels of noxious

stimuli are increasing levels of sedation required?

MR. SUTHERLAND: Object to the form.

THE WITNESS: As increasing levels of noxious stimuli, are increasing levels of sedation required. In what context?

MS. NELSON-MAJOR: In the clinical context.

THE WITNESS: And what's the noxious stimuli?

BY MS. NELSON-MAJOR:

Q. Well, starting with a conscious sedation, you talked about cardiac catheterization. If we're talking about open heart surgery, obviously an increased level of sedation would be required for that, correct?

A. That's correct. I wouldn't disagree with that.

Q. And that's because the stimulus of having an open heart surgery is greater than the stimulus of having a cardiac catheterization; is that correct?

A. Correct. I would say a saw going through a chest is different than a catheter in the femoral vein.

Q. And so following a rapid sequence

induction, if the doctor had to perform an additional procedure on the patient, would additional sedation need to be administered?

MR. SUTHERLAND: Object to the form.

THE WITNESS: It would depend on what they're performing, I guess.

BY MS. NELSON-MAJOR:

Q. And if what they were performing was a painful procedure, would additional levels of sedation be required?

MR. SUTHERLAND: Object to the form.

THE WITNESS: I would default to the physician. I don't know the procedure, is it they're intubating before a cath or they're intubating before cardiac surgery.

MS. NELSON-MAJOR: Mr. Sutherland, did you receive that article?

MR. SUTHERLAND: I'm still waiting for it.

MR. KURSMAN: I sent it a few minutes ago, so hopefully it's --

MR. SUTHERLAND: Yeah, I still haven't -- it still hasn't come through.

MS. NELSON-MAJOR: Maybe now would not be a bad time to take a ten-minute break. We

can wait for that e-mail to come through and --

MR. SUTHERLAND: Sure. Yeah.

VIDEOGRAPHER: Going off the record, the time is 2:23.

(A brief recess was taken.)

VIDEOGRAPHER: Back on the record, the time is 2:36.

BY MS. NELSON-MAJOR:

Q. Dr. Patel, before we took a break we were talking about your opinion that midazolam is an acceptable first drug in the lethal injection protocol because it's used as the first drug in RSI, and we were looking at this Renew article because it's the article you support -- cite for support for that proposition. Do you have that article in front of you?

A. I do, yes.

Q. And I'm going to mark the Renew article as Exhibit 16, I believe. Yeah, Exhibit 16.

Can you explain to me how this article supports your conclusion that because midazolam is the first drug in RSI, it's the appropriate first drug in Tennessee's lethal injection protocol?

A. This particular paper references

neuromuscular blockade in a therapeutic context, which is the same as -- in the ICU, which is the same as RSI, in which midazolam is used as an induction agent, or can be. Oh, sorry, go ahead.

Q. Please finish. I thought you were done.

A. There's two different premises. The RSI is a one-time procedure, similar I guess in con-- in some context to execution because it's a one-time procedure. And in this particular circumstance, this is comfort and sedation while the patient's getting neuromuscular blockade, which midazolam is also used for. It's just another use for the same purpose and principle.

Q. And does this article specifically discuss midazolam?

A. Does it specifically discuss midazolam? No, it discusses neuromuscular blockade in the critically ill, on the mechanical ventilator, the different neuromuscular blockers and their dosages.

Q. And does this article discuss rapid sequence induction?

A. It does not discuss rapid sequence induction, no. That was the product labeling. It does discuss sedation strategies, though.

Q. I want to turn to page nine.

A. Sure.
Q. I'd like to draw your focus to the heading: Sedation strategies.
A. Okay.
Q. Do you see that section?
A. I do, yes.
Q. Do you see that it says, "A comprehensive review of sedation strategies in the ICU is beyond the scope of this review. Nonetheless, vigilance is warranted in maintaining adequate sedation when NMBAs are utilized in order to avoid unintended patient awareness and recall."
And NMBA is neuromuscular blocking agent; is that correct?
A. That's correct.
Q. And so how does this article that explicitly states that they're not discussing sedation strategies in the ICU support your conclusion that midazolam's an appropriate drug for TDOC to use?
A. It's just another description of how neuromuscular blockers are used in the ICU. In this case it's to facilitate mechanical ventilation. We've already talked about the other ones that are in the product labeling.

Q. And how does an article about use of a neuromuscular blocking agent in the ICU support the analogy you're drawing between RSI and the lethal injection protocol?

A. It's not. They're all together. So in order to utilize neuromuscular blockade in the ICU, they're sedated. This article focuses specifically on the neuromuscular blockers and their monitoring.

Q. And this article is explicitly stating that they're not discussing what sedation is necessary or adequate to protect against awareness following a neuromuscular blocking agent, correct?

A. That's correct.

MR. SUTHERLAND: Object to the form.

THE WITNESS: That's correct. Go ahead.

BY MS. NELSON-MAJOR:

Q. So how does an article that does that address the adequacy of midazolam in the context of TDOC's use of vecuronium bromide followed by potassium chloride?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: This is discussing long-term neuromuscular blockade. The other one, which is more relevant, is RSI which we've

already gone over.

BY MS. NELSON-MAJOR:

Q. But I'm asking you about this article because you cited it for the proposition that because midazolam is used as the first drug in RSI, it is appropriate as the first drug in the lethal injection protocol. And I'm trying to understand how this article supports that analogy.

A. It's just describing another utilization of neuromuscular blockers in the clinical context. In this case it's for management in patients in the unit.

Q. The opinion that you're offering comparing RSI and the lethal injection protocol is made in order to support your conclusion about the adequacy of sedation in the protocol, correct?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: The depth of the sedation will be achieved based on the use of a benzodiazepine before a neuromuscular blocker, that's correct, as done in RSI.

BY MS. NELSON-MAJOR:

Q. And this article does not discuss sedation strategies, correct?

MR. SUTHERLAND: Object to the form.

THE WITNESS: That's correct. This is not a review of sedation analgesia. That's discussed in the critical care medicine guidelines, which were the PADIS guidelines that got published in 2018.

BY MS. NELSON-MAJOR:

Q. And do you cite those guidelines in your report?

A. Did I cite them? No. Are we aware of them in clinical practice and do I use them daily? Yes, absolutely.

Q. And are you saying that there's something in those guidelines that support the comparison you're drawing between RSI and the TDOC's lethal injection protocol?

A. No, I'm saying that those guidelines actually substantiate and support the use of midazolam as a benzodiazepine for patients who are neuromuscular blocked, in the ICU setting, on the mechanical ventilator.

Q. And do those guidelines discuss whether midazolam is an adequate sedative before administering potassium chloride?

A. No, because that's outside of a clinical context. There is not a study or a piece of

literature I'm aware of where clinicians are giving midazolam, or any benzodiazepine, before potassium chloride, or actually any drug, at least that I'm aware of.

Q. And this Renew article, therefore, also does not discuss sedation strategies prior to administration of potassium chloride, correct?

A. That's correct. I've already stated, I'm not aware of any medication trial in a clinical context where a drug was given before a potassium chloride infusion --

Q. And, in your opinion --

A. -- because it's not done.

Q. -- what would administration of 240 mil equivalents of potassium chloride feel like to an awake person?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: I don't know what it would feel like, because we don't do it in a clinical context. I don't know if it's ever been described.

BY MS. NELSON-MAJOR:

Q. Dr. Patel, are you a pharmacist or a pharmacologist?

A. Both, by training and experience.

Q. And what's the difference between those two fields?

A. Well, it's actually a continuum. If you're familiar with pharmacy. So pharmacists actually get six years of academia before going into practice these days, and some colleges it's seven. But the reason I mention that is, it's heavily pharmacology focused, up to about three to four years' worth, before they're put in the direct patient care setting, where we interact with the healthcare team and patients at the bedside or in at outpatient setting.

Pharmacologists, because we -- I actually have taught in that curriculum, is more laptop and bench based, it's research; there's no human interaction, there's no patients, but there is teaching of the concepts, of which we've already gone over, which are, again, the exact same in pharmacology within pharmacy, which is pharmacokinetics and pharmacodynamics, so how drugs are broken down in the body and then, pharmacodynamics, what their clinical impact is when they're given.

Q. And are there different educational requirements for a pharmacist versus a

pharmacologist?

A. They are two different degrees, that's correct. Only one is recognized professionally.

Q. And what are the two different degrees?

A. Doctorate of pharmacy, which I possess, and a doctorate of philosophy in pharmacology, which is Ph.D. One is registered, one is not.

Q. What do you mean by registered?

A. We register and licensure and are authorized individually by state. I'm not aware of any professional regulation over pharmacologists. So there's a big distinction, because we actually work with patients.

Q. And in order to be registered as a pharmacist you need a Pharm.D.; is that correct?

A. It would be Pharm.D., or two decades prior it would be registered pharmacist or RpH, that's correct, it would be one of the two.

Q. And how many years of graduate school did it take for you to earn your Pharm.D.?

A. Well, it's -- to backtrack, it's a lineage. So it was first the chem degree, which was four years, the pharm degree -- Pharm.D. degree, which was six, residency training added on an extra year, seven, and a master's which I produced, went

thereafter, which was two years. So in total, gosh, 8, 12, 13 years of school.

Q. And what was your master's degree in?

A. Clinical research.

Q. And what was your undergraduate degree in?

A. Chemistry.

Q. And have you completed any coursework since you attained your Pharm.D.?

A. Coursework? I'm not sure that I understand. You mean like continuing education?

Q. I meant as far as you took classes to get your Pharm.D. Did you take any other graduate-level classes?

A. Besides my master's course, no. But Pharm.D.'s, which are distinctly different from Ph.D.'s, we have a requirement of CE, which is continuing education, where you keep up on scientific literature just like this.

Q. And how many hours a year are you required to do your continuing ed?

A. It's 30 years (sic) of continuing education ever year.

Q. Thirty hours per year?

A. That's what I recall and understand, that's correct.

Q. And --
A. It varies by state.
Q. What states are you licensed in?
A. I'm licensed in the state of Illinois and the state of Missouri, where I did my training.
Q. And you also hold several certifications; is that right?
A. That's correct.
Q. And one is a BCPS, correct?
A. That's correct.
Q. And what is that certification?
A. It's Board Certified Pharmacotherapy Specialist. It's again done by examination, and then you actually have to submit 100 hours every seven years of continuing education, unless you want to subject yourself to taking the exam again. But it revolves around therapy in the general sense of adults, pediatrics, could be oncology, it could be men's health, women's health, etcetera.

But it's, again, being certified to look at those medications and how they interact with laboratory values in the disease state and their clinical outcome.

Q. And in order to first obtain that certificate, you had to pass an exam?

A. That's correct, it requires licensure and pass of examination. And thereafter, I thought it was every seven years, you can either do -- you could submit like 100 or 120 CE hours or, if you want to, you could subject yourself to another exam.

Q. And is that certification specific to sterile compounding?

A. Sterile compounding is included in there, as well as total parenteral nutrition.

Q. Do you hold a Compounded Sterile Preparations Certificate from the American Society of Health System Pharmacists as well?

A. I do not, no.

Q. You also have a BCCCP; is that right?

A. That's correct.

Q. And what's that certificate?

A. Different than the first but the same organization, it's board certification in critical care pharmacotherapy. So it involves, encompasses everything from the Intensive Care Unit in the perioperative space, known as the operating room, looking at the same things; again, the interaction between laboratory values, medications and disease states, and coming up with a therapeutic plan for patients and communicating that with providers.

Q. And how did you obtain that certification?
A. That was -- it was first offered, if I remember right, in twenty -- the fall of 2015. And that was by examination as well. And that is coming up for renewal at the end of this year.
Q. And is the renewal another exam?
A. That is one option. You can subject yourself to the pleasure of another exam or you can submit 100 hours.
Q. And what is your FCCP certificate?
A. It's fellowship credentialing and approval in the College of Clinical Pharmacy, which is under the organization of the American College of Clinical Pharmacy, which encompasses a numerous of therapeutic issues that we're discussing, in terms of the drug activity and their action in patients and/or preparations of drugs.
Q. And when did you first obtain that certificate?
A. The fellowship, I was chosen and awarded just this past fall. It would have been in 2020.
Q. And when you say awarded, how is that awarding made?
A. Pharmacists can't just apply, you have to be selected.

Q. And what about the FCCM?
A. That's a fellow in the College of Critical Care Medicine, so that's within the Society of Critical Care Medicine, which again encompasses the adult Intensive Care Unit and therapeutic issues within the perioperative space, known as the operating room.
Q. Have you ever taken the Board of Pharmacy's compounded sterile preparations specialty certification exam?
A. No, I have not.
Q. And you're not a medical doctor, right?
A. No. And I'm okay not being one.
Q. And as a pharmacist, are you authorized to write a prescription?
A. We are, actually, in the context of collaborative practice agreements, that is true.
Q. And what is a collaborative practice agreement?
A. It's where physicians actually will authorize pharmacists to take over the prescription, monitoring, and dosing of different medications inside or outside of a hospital.
Q. And do those agreements authorize a pharmacist to write a prescription for all drugs?

A. Negative. The collaborative practice agreement would outline which medications.

Q. And are you part of a collaborative services agreement?

A. We have collaborative privileges, that's correct, for different services we offer in the hospital in a therapeutic setting, that's correct.

Q. And so do you on occasion write prescriptions for drugs?

A. It's not necessarily writing the prescription for the drug, it's -- for example, the physician can only type in one word in the computer, not the dose, not the monitoring, not the laboratory values, but the pharmacist takes over everything after that one word or order is entered.

Q. And are those agreements generally limited to a certain class of drugs?

A. It could be three, four, five, ten. It depends on the hospital.

Q. And what is your services agreement for, which drugs?

A. Ours are inclusive of antibiotics, specifically vancomycin and aminoglycosides, and it's also inclusive of an anti-coagulant warfarin, or Coumadin.

Q. And are those the only two categories?
A. Those are the ones currently approved, that's correct.
Q. And are you authorized to diagnose a patient?
A. I guess -- I apologize, I don't understand that. We don't -- I don't diagnose patients, no.
Q. Do you hold any other professional licenses?
A. No, ma'am.
Q. Do you have any other medical training outside of what we've already discussed?
A. No, ma'am.
Q. You're currently employed by the University of Chicago Medicine system; is that correct?
A. That's correct, yes, ma'am, I'm a full-time clinician.
Q. And how long have you been employed by the University of Chicago?
A. University of Chicago? It'll be -- I've been there now two years.
Q. And what's your position there?
A. I'm within -- I'm a clinical coordinator within the critical care and the perioperative

areas.

Q. And for the critical care area, are you the only clinical pharmacist?

A. Oh, gosh, no. It's a busy hospital. There's probably at least almost half a dozen of us.

Q. And what do your duties entail as a clinical pharmacist for the critical care area?

A. It's direct patient care, so you work with the nurse, the physician, sometimes a mid-level provider. And it's reviewing the patient's medications, their laboratory values, the disease states, the notes in the chart, and coming up with a therapeutic plan balancing the efficacy of the drug and the safety.

Q. What percentage of your day is spent in the pharmacy versus at a patient's bedside?

A. I am a hundred percent at the bedside. It's because we have a hybrid model. So we actually approve drug orders for patients on our floor or other Intensive Care Units during the course of your entire day. So you actually perform operational and clinical duties at the same time Monday through Sunday.

Q. Do you personally compound drugs in your role as a clinical pharmacist at the University of

Chicago?

A. On occasion, yes, we have to.

Q. And who normally does the compounding of preparations? I'm not asking for a name, I'm asking for their role at the hospital.

MR. SUTHERLAND: Object to the form.

THE WITNESS: It would be a pharmacy technician, unless the pharmacy technician is not there or there's not one stationed in your satellite, then it'd be the pharmacist, or it's an emergency, which happens often.

BY MS. NELSON-MAJOR:

Q. And you don't personally administer the drugs at the patient bedside, correct?

A. I have and do not, except in one circumstance.

Q. And was that an emergency circumstance?

A. Correct, cardiac arrest, or RSI.

Q. Excuse me? Can you explain? You said there was one circumstance, cardiac arrest or RSI. Have you personally administered drugs during an RSI?

A. That's correct, it would be in an emergency. So if the provider -- if there's only one anesthesia resident, you're helping them

actually to draw up the drugs and the doses, so that can be pushed quickly into the IV line so they can perform the intubation safely. Those would be the emergency -- emergent situations only. Outside of that, no.

Q. And to clarify, have you in fact administered drugs during an RSI?

A. Over the last 20 years, yes. I can't remember the number of times, but it's happened. Cardiac arrest probably more frequently.

Q. And you also serve as the clinical pharmacist for the perioperative area; is that right?

A. Yes, ma'am.

Q. And what does perioperative mean?

A. It's a fancy word for the operating room and procedural area.

Q. And in this capacity do you personally determine the level of sedation or anesthesia required for a particular procedure?

MR. SUTHERLAND: Object to the form.

THE WITNESS: Do we deter-- do I determine the depth anesthesia. No, ma'am, that's determined by the anesthesiologist or the resident or the CRNA.

BY MS. NELSON-MAJOR:

Q. And once the anesthesiologist or CRNA makes that determination, are you the person who decides which drugs are the best choice for achieving that particular level of sedation or anesthesia?

MR. SUTHERLAND: Same objection.

THE WITNESS: No, ma'am, unless they have a drug they don't -- they can't get or they're out of or it's on shortage, which unfortunately occurs these days.

BY MS. NELSON-MAJOR:

Q. And so outside of those circumstances, who decides which drug will be appropriate to achieve a desired level of sedation or anesthesia?

A. In the clinical hospital setting, it would be the anesthesiologist or their resident or the CRNA.

Q. And once that decision about which drug to use has been made, are you in the operating room when it's administered?

A. That's correct, I have been in the operating room and been able to see medications administered by every discipline.

Q. And as part of your routine day-to-day

duties, are you normally in the operating room when those drugs are administered?

A. That's correct, that's our purpose of being there.

Q. I'm looking at page two of your report.

A. Okay.

Q. And I'm looking at the first full paragraph, which starts, "In addition to my intensive care duties." Do you see that paragraph?

A. I have, yes.

Q. And I'm looking at the last sentence in that paragraph, where you state that your role as a clinical pharmacist in the perioperative area requires a familiarity with drugs quote, "[used] in Anesthesia Pain Management, generally and the specific drugs in Tennessee's Lethal injection procedures (midazolam, vecuronium bromide and potassium chloride)."

What does anesthesia pain management mean?

A. Anesthesia pain management is just a subsection of anesthesia.

Q. Is vecuronium bromide a drug used in anesthesia pain management?

A. Within the operating room prior to surgical incision, that's correct.

Q. And what about midazolam, is it used as an anesthesia pain management?

A. That's correct, it would be the pre-sedative generally given as a dose of one to two milligrams, unless it's used for induction, it would be higher.

Q. And what about potassium chloride, is it a drug used in anesthesia pain management?

A. If they are covering a cardiovascular room, that is correct, it would be given outside of what the perfusionist is giving in response to a low potassium level.

Q. And does anyone report to you in your role as a clinical pharmacist?

A. No, ma'am.

Q. And do you report to anyone?

A. I report to the executive director, that's correct.

Q. What percentage of the drugs dispensed under your supervision as a clinical pharmacist are compounded?

A. It would depend on the setting, scenario, and circumstance.

Q. I'm asking about your job at the University of Chicago Medicine, the circumstance

being your role as a clinical pharmacist. I'm asking about whether in that setting and under that scenario, what percentage of drugs are compounded versus commercially manufactured.

A. Sure. Within the Intensive Care Unit it's probably majority clini-- manufacturer, commercially manufactured medications and drugs. Within the perioperative space up to 25 percent to 50 percent could be compounded preparations.

Q. And of the compounded drugs in that perioperative area, what percentage would you say are high-risk sterile preparations?

A. About 50 percent, half of them. It depends on which supplier you're getting it from. Majority are 503B, which are taking it from non-sterile to sterile preparations, which is what we use.

Q. You also list clinical coordinator anesthesia and surgery on your resumé. What are your duties in that capacity?

A. It's again working with the healthcare providers, directly with the anesthesiologists, the surgeons, and the Intensive Care Unit physicians, and putting together a therapeutic plan. Especially, when you have drug shortages; for

example, right now it's midazolam and potassium chloride.

Q. And outside of your role as a clinical pharmacist and a clinical coordinator, do you have any other duties at the University of Chicago?

A. Outside of taking care of 30 surgical, trauma and burn ICU patients in the perioperative area, which is encompassed of about 100 cases a day, no.

Q. Prior to your current job at the University of Chicago, where were you employed?

A. I was at Rush University Medical Center.

Q. And what titles did you hold while employed at Rush Medical Center?

A. I was the supervisor over the critical care and the perioperative area. And I also worked within different colleges for teaching, and that was inclusive of the medical college, the graduate college, which actually teaches Ph.D. students, CRNAs, which are certified registered nurse anesthetists, taught in that -- teach in that program. And I was the course director for the perfusionists, which actually administer cardioplegia.

Q. And what topics did you teach in those

capacities?

A. Everything related to medications, anesthetics, cardioplegia, and drug metabolism. So it would be inclusive of pharmacokinetics, how the drugs are broken down after they're given to the patient; and pharmacodynamics, the clinical effect after these medicines have been given in their context in the setting.

Q. How long were you employed at Rush?

A. Gosh, it was the first job when I graduated. So probably 18 years.

Q. And what motivated you to leave Rush?

A. There was a research opportunity and platform at the University of Chicago, and their grant endowment is significantly larger.

Q. Were your clinical duties at Rush different than your clinical duties at the University of Chicago?

A. No, the clinical duties are the same.

Q. How much of your time at Rush was devoted to teaching versus clinical duties?

A. Teaching probably could be 10 percent, 15 percent, depends on the part of the year and the course.

Q. And outside of your job at University of

Chicago and Rush, you've also served as an expert witness; is that right?

A. Yes, ma'am.

Q. How long have you been doing expert witness work?

A. That'd be north of 15 years.

Q. Approximately how many times have you been deposed?

A. I don't recall. It'd probably be north of a hundred.

Q. And can you approximate how many times you've testified at trial as an expert witness?

A. Probably north of 50.

Q. Prior to this case, have you been involved in any case in which a Department of Corrections was involved?

A. No, ma'am, I don't believe so, not that I recall.

Q. And is this the first lethal injection case in which you've been involved?

A. As far as I can remember and I'm aware, yes, that's correct.

Q. Who contacted you about getting involved in this case?

A. I would believe it was Mr. Mitchell.

Q. And do you remember when that conversation occurred?

A. No, I don't. It was at least a year ago, maybe more.

Q. What is your view on the death penalty?

A. Well, I'm a U.S. citizen, and if it's verified and allowed via the Constitution, and I support the Constitution, I'd support it.

Q. What percentage of your time is devoted to expert work versus your other duties at University of Chicago or Rush?

A. About 10 to 20 percent. Just depends on the year.

Q. Do you recall being retained by a man named Kenneth Hail, who alleged that Aleve, manufactured by Bayer, caused him permanent kidney issues?

A. I do not, no, ma'am.

Q. So you don't recall being deposed in that case?

A. I don't. I don't recall the case. I apologize.

Q. Are you aware of any cases in which the judge has disqualified you from offering an opinion in a case?

A. If they have, I'm not aware of it. So, no, ma'am, I don't know.

Q. I'm trying to pull up your report. If we could go to the last page.

A. Okay.

Q. What is this list?

A. Oh, you mean the last page of the report. One second.

Q. I'm sorry, the pdf, not the actual report.

A. Got it. Let me get there. I'm sorry. I was asked to provide a list of cases in the last four years.

Q. And how did you come up with this list?

A. I did the best from my memory and from what I could scavenge through my e-mails.

Q. Do you recall being involved in a case involving allegations that a flu vaccine caused the death of a woman named Susan Halverson?

A. That does sound familiar, yes.

Q. Did you provide testimony in that case?

A. That does sound familiar, that's correct. I think it was a number of years ago.

Q. Why was that case not included on your list here?

A. Well, I thought it said last four years.

And if I remember right, I thought that one was before that. I don't recall what year I testified.

Q. The Attorney Generals who retained you in this case indicated that you participated in some capacity in a case captioned: Shawn Taylor versus Medical -- sorry, excuse me, Mercy Medical Center, out of Maryland. Do you recall that case?

A. I don't, no, ma'am.

Q. I am pulling up a deposition transcript that we'll e-mail to you, Mr. Sutherland.

MR. SUTHERLAND: Thank you.

Q. And while we're waiting for that to come through, I wanted to ask a follow-up question. You testified that we don't know what 240 mil equivalents of potassium chloride would feel to an awake person, correct?

A. 240 mil equivalents split up into 60 cc's, so 120 actually at a time? No, I don't know what that would feel like in that concentration.

Q. So did you consider potential effect of potassium chloride would have on the inmate when you opined that midazolam was an appropriate first drug in the TDOC protocol?

A. I did, yes. Because my opinion is, is that the inmate would be rendered insensate,

unconscious and unable to respond to physical stimuli.

Q. And if you don't know what the potassium chloride would feel like when administered, how do you know what level of sedation would be appropriate to render an inmate insensate to that unknown, according to you, stimulus?

A. Based on 250 milligrams given intravenously about a minute apart would render a person unconscious and unable to respond to physical stimuli.

Q. And it's your opinion that regardless of the severity or magnitude of a stimulus presented by the potassium chloride, that dose of midazolam would be adequate.

A. 250 milligrams intravenously, set apart by about a minute, given in total of 500 milligrams, yes, ma'am, that would be adequate.

MR. SUTHERLAND: I just sent the transcript.

A. Okay.

Q. I'm going to mark this transcript as Exhibit 17.

Do you recall being deposed in this case captioned: Estate of Elena Chavez versus Dignity

Health?

A. I don't, no.

Q. And why was it not included on your list of cases in which you've offered testimony in the last four years?

A. I think I just told you, it's because I don't recall the case. I don't have any record.

Q. And you earlier said that you reviewed your e-mail when compiling this list; is that right?

A. That's correct.

Q. And can you explain to me how you went about reviewing your e-mail to compile the list of cases in which you've testified?

A. Yeah, I basically looked at the inbox or anything sent, because the trash is completely empty. So I tried to find whatever I could the best way I could to supply a list. And so I put forth a good faith effort to do so.

MS. NELSON-MAJOR: Mr. Sutherland, Dr. Patel, can we take a five-to-ten-minute break? I'm nearly finished, but I just want to --

MR. SUTHERLAND: Yeah, sure. Like -- whatever you like.

MS. NELSON-MAJOR: 3:30/4:30?

MR. SUTHERLAND: Yep, that's fine.

VIDEOGRAPHER: Going off the record, the time is 3:18.

(A brief recess was taken.)

VIDEOGRAPHER: Back on the record, the time is 3:33.

BY MS. NELSON-MAJOR:

Q. Dr. Patel, I want to ask you a couple more questions about your previous expert testimony work. Do you keep copies of the expert reports that you write in these cases?

A. No, ma'am, due to, I believe most of them now, for the last 10, 15 years come with -- at least 10 years for sure -- HIPAA agreements that you destroy all materials related to the case. So whether it does or not, it's an active practice, I just -- they go to the shredder. Some companies/ firms want them sent back, so you send it back.

Q. And when you write an expert report in a case, how do you provide it to the attorneys that have retained you?

A. Usually it's e-mailed, unless it's discussed over the phone.

Q. So in some cases you provide your expert report over the phone?

A. It would be discussing my thought processes and opinions on the phone, that's correct.

Q. And do you go through and delete the e-mails that you've sent to attorneys providing them with expert reports?

A. I do. I don't have a reason to keep them, so I get rid of it. It just clutters the e-mail.

Q. And how soon after you provide a report to an attorney in a case do you delete that e-mail?

A. Probably after I sent it. I don't have any use for it.

Q. And so as soon as you send an e-mail to an attorney in a case, you then go ahead and delete the e-mail, the sent e-mail?

A. After I'm done sending any e-mail, if I've deleted it, the trash is emptied. So, yeah, I don't have any reason to keep any of that stuff, it's gone.

Q. No, my question is, how soon after sending the e-mail with your report do you then go and delete that sent e-mail from your e-mail account?

A. Oh, I see what you -- I don't do anything. Gmail does it all, it's already gone.

Q. So you're saying that Gmail automatically deletes your sent mail?

A. You can set it up that way, that's correct, so it doesn't clutter your box.

Q. And so you have your Gmail set up to automatically delete an e-mail as soon as you send it?

A. Sent and anything put in trash.

Q. So are you saying that Gmail deletes the e-mail for you automatically or you delete the sent e-mail?

A. I don't delete anything. It was set up so I -- because I had too much clutter in the e-mail inbox.

Q. I'm talking about your sent mail folder, not your inbox. You have Gmail set up to automatically delete every e-mail that you send?

A. The inbox one, I believe, is like on a rotation. The sent, I believe, if I remember right, was something like 30 or 60 days. The trash is automatically emptied once it goes in there.

Q. And when you searched your e-mails for the cases in which you previously testified over the past four years, did you type in a search word or did you manually scroll through your inbox?

A. No, I just tried to look for either sent invoices or things like that.

Q. Do you keep copies of your billing records in these cases?

A. No. No, ma'am, unless -- not unless they're active.

Q. So you delete your billing records as soon as you're done with a case?

A. Yeah, I don't have any need for them. They send -- I forget the name of the form, but they send it every January or February and then that just goes to the accountant.

Q. Who's "they"?

A. The firm sends whatever, I forgot the form, W-9 or something like that, for taxes.

Q. And so when the firm sends you a W-9, you forward it to your accountant?

A. Well, I don't -- they don't -- they send it via paper mail or snail mail, and then I have to huck all of those over to the accountant, they take care of it, and then the accountant has it on file, I'm sure.

Q. And do you not keep any records of your billing besides the one that you've send to the accountant?

A. No, I don't, ma'am.

Q. Do you report the income that you earn

through your expert work to the IRS?

A. Yes, ma'am, as required.

Q. Do you keep copies of your tax records?

A. I keep copies of my tax records, yes, ma'am.

Q. And for the documents that you receive from attorneys on these cases, what do you do with those documents?

A. Are these active cases or completed?

Q. Let's start with active cases. What do you do with documents when you receive them from an attorney while the case is active?

A. Well, majority now is ShareFile. So they're just different links that are sitting in the e-mail system.

Q. And then when the case is no longer active, what do you do with the documents?

A. I don't do anything, except delete the e-mail for the link for the ShareFile, whether it's -- it's generally like a firm secure link, it could be Dropbox, those kinds of things.

Q. And how do you know when a case is no longer active?

A. They will let you know.

Q. And who's "they"?

A. The firm that hired me.
Q. So once you're told that a case is no longer active, you go through and you delete the particular e-mail with the ShareFile link; is that correct?
A. That's correct. And if they sent anything over in paper, it goes to the -- next time I take it to the shredder.
Q. And you delete the copy of the reports that you send via e-mail?
A. That's correct. I don't have any use for those.
Q. And you delete the drafts of the report that you might have saved on your computer?
A. That's correct.
Q. And you delete all the invoices that you've sent to the attorneys?
A. At that time point, that's correct, after everything's been submitted and paid.
Q. And to do that, do you go back through your e-mail to find every e-mail related to a particular case and delete it?
A. That's correct.
Q. And do you do that because you have a document retention policy that says that you should

be doing that?

A. Correct. To expand, it's inclusive of HIPAA. And in my world, where we actually work with humans and patients, HIPAA is anything with the patient name or an identifier. The invoice has that information, so I delete it and I honor what they ask.

Q. And so you're saying that HIPAA governs your expert witness work in these cases.

A. No, I'm saying I'm concerned about patient information and identifiers. And in my world, anything that connects a case to a patient, I would think is an identifier. So I remove it because I have no need for it, and I don't want anything attached in violation of that. And so I respect whatever they ask me to do.

Q. And "they" being the firm?

A. That's correct. It could be a plaintiff firm or a defense firm.

Q. And so those firms have instructed you to delete all of this information once the case is closed?

A. That's correct. It's a general statement of "Delete all records." And, to me, all records is anything related to the case in the file.

Q. Do you have a secretary?
A. No, ma'am, I don't have a secretary.
Q. And when you're working on a case, how do you keep track of the time that you're billing?
A. A Post-it, usually.
Q. So you have a series of Post-its on your desk for each case that you're currently working on?
A. No, right now I don't have any. It's a Post-it on a case of anything that I'm actively reviewing, and once I've compiled the hours, similar to today, I would just send the invoice and throw the Post-it out, gets shredded.
Q. Are you keeping track of the hours that you worked on this case on a Post-it note?
A. That's correct. Not a Post-it note. I actually have a Word document, because it's been -- since my last invoice it's probably been at least two months, maybe a month and a half.
Q. Do you delete your Word documents with the hours that you work on a case after it's closed as well?
A. That's correct. I don't have any reason for any of those. Once it's been paid.
Q. How many invoices have you submitted in this case?

A. I think one, which was, I thought, back in December. And I haven't prepared the second. I've started to.

Q. Have you already deleted the invoice that you created in this case?

A. I believe so. But I believe the -- the office has it. I'm sure they can provide it, if you want.

Q. So if you delete your invoices as you go, how do you know that the firm or the attorney that's retained you is paying the appropriate amount?

A. I only get rid of it after it's been paid, and it's been paid, so I don't have any need for it.

Q. Have you been required to prepare the type of list that we just were talking about, on the cases in which you've testified previously, in other cases?

A. Over the last 15 years, I'm sure I've been asked to, yes.

Q. And do you also delete those lists after you prepare them?

A. After they're sent, that's correct. I don't have any need for it.

Q. Dr. Patel, in your opinion, will 500 milligrams of midazolam be sufficient to render

a patient insensate to the painful -- to painful surgical stimulus?

MR. SUTHERLAND: Object to the form.

THE WITNESS: My opinion is, is that it will render a person unconscious and unable to respond to physical stimuli.

BY MS. NELSON-MAJOR:

Q. My question was more specifically, would it be sufficient to render someone insensate to painful surgical stimuli?

MR. SUTHERLAND: Objection to the form.

THE WITNESS: Surgical stimuli? You'd have to ask a surgeon.

BY MS. NELSON-MAJOR:

Q. So you're rendering an opinion that 500 milligrams will be sufficient for a physical stimulus in general, but you're not able to render an opinion on the particular question of whether it would render a someone insensate to a painful surgical stimulus?

A. That's correct, because surgical, depends on the procedure, and I'm not a surgeon.

MS. NELSON-MAJOR: Can we take a two-minute break? I think we're about done. But if we could take a two-minute break and go

off the record, then we should be able to finish.

MR. SUTHERLAND: Sure.

VIDEOGRAPHER: Off the record, the time is 3:44.

(A brief recess was taken.)

VIDEOGRAPHER: Back on the record, the time is 3:46.

MS. NELSON-MAJOR: I have no further questions for Dr. Patel. But I do want to thank Dr. Patel for his time today, so thank you.

MR. SUTHERLAND: Thank you, Ms. Nelson-Major, and thank you everybody else. Hope you have a good weekend.

THE WITNESS: Appreciate it. Thank you.

MS. NELSON-MAJOR: Thank you, Mr. Ely and Ms. Davis.

VIDEOGRAPHER: This is the conclusion of the deposition, the time is 3:47, going off the record.

(Off the record and deposition concluded.)

C E R T I F I C A T E

STATE OF TENNESSEE )
)
COUNTY OF KNOX )

I, Brenda L. Davis, LCR, RPR, RMR in and for the State of Tennessee, do hereby certify that the above deposition was reported by me and that the foregoing # pages of the transcript are a true and accurate record to the best of my knowledge, skill, and ability.

I further certify that I am not related to nor an employee of counsel or any of the parties to the action, nor am I in any way financially interested in the outcome of this case.

I further certify that I am duly licensed by the Tennessee Board of Court Reporting as a Licensed Court Reporter, as evidenced by the LCR number and expiration date following my name below.

Brenda Davis

Brenda L. Davis, LCR# 806

Expiration Date: 6/30/2022

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Tennessee Rules of Civil Procedure

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Rule 30

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